

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

MORTON GROVE )  
PHARMACEUTICALS, INC., )  
vs. Plaintiff, ) No. 08-CV-1384  
vs. ) Judge Bucklo  
THE NATIONAL PEDICULOSIS ) Magistrate Judge Mason  
ASSOCIATION, INC., )  
Defendant. ) **JURY TRIAL DEMANDED**

**OPPOSITION TO MORTON GROVE PHARMACEUTICALS, INC.'S MOTION TO  
DISMISS THE NATIONAL PEDICULOSIS ASSOCIATION, INC.'S COUNTERCLAIM**

**INDEX OF EXHIBITS**

- Exhibit 1      Excerpt from Closerlook website
- Exhibit 2      Excerpts from mgp-online.com (now wockhardtusa.com)
- Exhibit 3      Excerpts from lindane.com

# EXHIBIT 1

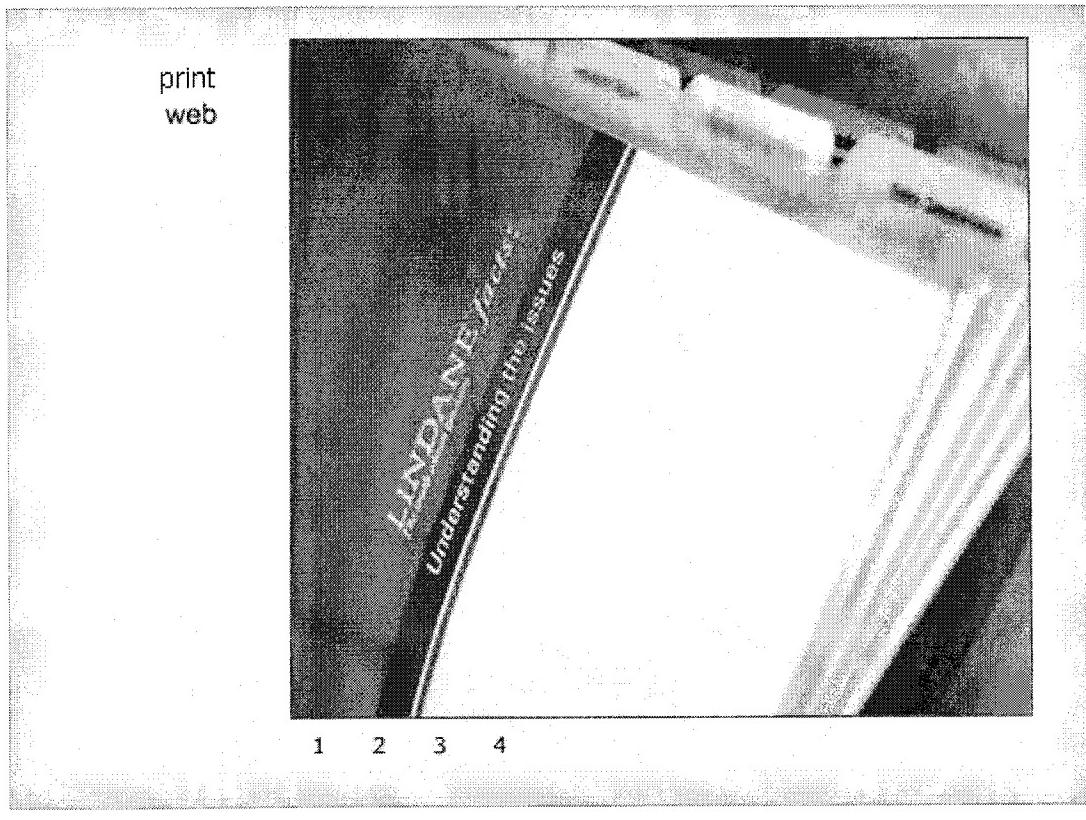
Company	Capabilities	Industries	Perspective	Contact
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Home: Capabilities: Portfolio: Mgp

# Morton Grove Pharmaceuticals

Morton Grove Pharmaceuticals, Inc., is a specialty pharmaceutical company that develops, manufactures and markets prescription oral liquid and topical liquid pharmaceuticals. The company manufactures and markets over 50 products. Morton Grove Pharmaceuticals is a leading manufacturer and marketer of prescription oral liquid pharmaceuticals in the United States.

Morton Grove Pharmaceuticals was faced with the urgent task of addressing a misleading communications movement that was negatively impacting its business. Inaccurate and distorted information had affected MGP's bottom line sales of lindane, and had resulted in the banning of lindane-based drug therapies in the state of California. MGP partnered with closerlook to launch "The truth about lindane" integrated communications campaign, to prevent further bans in other states and avert additional losses of yearly sales for MGP's lice and scabies second-line drug therapies. The overarching goal of the communication campaign was to set the record straight on the safety and efficacy of lindane prescription therapies - as defined by the FDA - to various audiences. closerlook created printed materials for direct communication between lobbyists and legislators as well as communication between lindane representatives and healthcare professionals (HCPs). A website was produced that spoke to a broader audience of legislators, HCPs, consumers, school nurses, and the media.



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# EXHIBIT 2

Wockhardt USA - Our Other Websites Windows Internet Explorer provided by Jenner & Block

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Wockhardt USA - Our Other Websites

**WOCKHARDT usa**

ABOUT US PRODUCTS KNOWLEDGE CENTER NEWS & EVENTS CONTACT US HOME

**PRODUCTS**

Wockhardt USA and Morton Grove Pharmaceuticals offer a generic and branded portfolio of over 50 products in a variety of dosage forms, including oral solids, liquids, topicals and injectables. Most products are manufactured in one of Wockhardt's global facilities and all are FDA-approved. To learn more about the FDA approval process, see our [Knowledge Center](#).

[Click Here for a detailed product listing. \(PDF\)](#)

#### Wockhardt Name

Acetaminophen & Codeine Phosphate Oral Solution

Acetic Acid Otic Solution

Amantadine HCl Syrup

Amlodipine Besylate Tablets

Azithromycin Tablets

Bethanechol Chloride Tablets

Captopril Tablets

Carbamazepine Suspension

Cefotaxime for Injection

Cefprozil Tablets

Ceftriaxone for Injection

Cefuroxime Axetil Tablets

Cimetidine HCl Oral Solution

Clarithromycin Tablets

Clobetasol Propionate Topical Solution

Cyclosporine Oral Solution

Dexamethasone Elixir

Dexchlorpheniramine Maleate Oral Solution

Doxepin HCl Oral Solution

Enalapril Maleate Tablets

Erythromycin Topical Solution

Famotidine Tablets

Fluoxetine Oral Solution

Fosphenytoin Sodium Injection

Furosemide Oral Solution

Generlac Solution

Granisetron HCl Injection

Hydrocodone and Homatropine Syrup

Hydroxyzine HCl Syrup

Ketorolac Tromethamine Injection

Lactulose Solution

Lidocaine HCl Oral Solution

Lidocaine HCl Topical Solution

Lindane Shampoo

Lisinopril Tablets

Lithium Citrate Syrup

Megestrol Acetate Oral Suspension

Metoclopramide HCl Oral Solution

Myphetane DX Cough Syrup

Nystatin Oral Suspension

Ondansetron Injection

Oxybutynin Chloride Syrup

Phenytoin Oral Suspension

Phenytoin Sodium Extended Capsules

Prednisolone Sodium Phosphate Oral Solution

Promethazine Syrup Plain

Promethazine w/Codeine Cough Syrup

Promethazine w/DM Cough Syrup

Ranitidine Tablets

Selenium Sulfide Lotion

Sertraline HCl Tablets

Terbinafine HCl Tablets

Triamcinolone Acetonide Lotion

Valproic Acid Syrup

Zolpidem Tartrate Tablets

Zonisamide Capsules

#### Compares To

Tylenol w/Codeine®

VoSol®

Symmetrel®

Norvasc®

Zithromax®

Urecholine®

Capoten®

Tegretol®

Claforan®

Cefzil®

Rocephin®

Ceftin®

Tagamet®

Biaxin®

Temovate®

Sandimmune®

Decadron®

Polaramine®

Sinequan®

Vasotec®

Eryderm®

Pepcid®

Prozac®

Cerebyx®

Lasix®

Cephulac®

Kytril®

Hycockan®

Atarax®

Toradol®

Chronulac®

Xylocaine®

Xylocaine®

Kwell®

Zestril®

Cibalith-S®

Megace®

Reglan®

Dimetane-DX®

Mycostatin®

Zofran®

Ditropan®

Dilantin®

Dilantin®

Orapred®

Phenergan®

Phenergan w/Codeine®

Phenergan w/DM®

Zantac®

Seisun®

Zoloft®

Lamisil®

Kenalog®

Depakene®

Ambien®

Zonegran®

#### Therapeutic Category

Analgesic

Anti-infective

Antiviral

Calcium Channel Blocker

Antibacterial

Cholinergic Agent

ACE Inhibitor

Anticonvulsant

Antibacterial

Histamine H2-Receptor Antagonist

Antibacterial

Corticosteroid

Immunosuppressant Agent

Corticosteroid

Antihistamine

Antidepressant

Antidepressant

Antidepressant

Anticonvulsant

Diuretic

GI Agent

Antinauseant/Antiemetic

Antitussive

Antianxiety Agent

NSAID

GI Agent

Anesthetic

Anesthetic

Antiparasitic

ACE Inhibitor

Antimanic Agent

Antineoplastic

Prokinetic Agent

Antitussive/Antihistamine/Decongestant

Antifungal

Antinauseant/Antiemetic

Antispasmodic/Anticholinergic

Anticonvulsant

Anticonvulsant

Corticosteroid

Antihistamine

Antihistamine

Antitussive

Histamine H2-Receptor Antagonist

Antifungal

Antidepressant

Antifungal

Corticosteroid

Anticonvulsant

Sedative

Anticonvulsant

#### Product Line

Morton Grove

Morton Grove

Morton Grove

Wockhardt USA



## Wockhardt USA & Morton Grove Pharmaceuticals Product List



### **NDC #**

### **Product Name**

### **Strength**

### **Pack Size**

### **ANDA #**

### **FDA Rating**

### **Compares To**

### **Color/Shape**

### **Imprint**

### **Product Line**

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
60432-245-04	Acetaminophen & Codeine Phosphate Oral Solution	120/12mg per 5mL	118 mL	87-006	AA	Tylenol w/Codeine	Amber solution with cherry flavor	N/A	Morton Grove
60432-245-16	Acetaminophen & Codeine Phosphate Oral Solution	120/12mg per 5mL	473 mL	87-006	AA	Tylenol w/Codeine	Amber solution with cherry flavor	N/A	Morton Grove
60432-741-15	Acetic Acid Otic Solution	2%	15 mL	40-166	AT	VoSol	Colorless solution	N/A	Morton Grove
60432-093-16	Amantadine HCl Syrup	50mg/5mL	473 mL	75-060	AA	Symmetrel	Colorless to pale yellow syrup with raspberry flavor	N/A	Morton Grove
64679-421-01	Amlodipine Besylate Tablets	2.5 mg	90	78-500	AB	Norvasc	White to off-white, triangle-shaped tablet	W 421	Wockhardt USA
64679-422-01	Amlodipine Besylate Tablets	5 mg	90	78-500	AB	Norvasc	White to off-white, caplet-shaped tablet	W 422	Wockhardt USA
64679-422-02	Amlodipine Besylate Tablets	5 mg	1000	78-500	AB	Norvasc	White to off-white, caplet-shaped tablet	W 422	Wockhardt USA
64679-423-01	Amlodipine Besylate Tablets	10 mg	90	78-500	AB	Norvasc	White to off-white, round tablet	W 423	Wockhardt USA
64679-423-02	Amlodipine Besylate Tablets	10 mg	1000	78-500	AB	Norvasc	White to off-white, round tablet	W 423	Wockhardt USA
64679-961-05	Azithromycin Tablets	250 mg	6 x 3	65-404	AB	Zithromax	White, oval-shaped tablet	W 961	Wockhardt USA
64679-961-01	Azithromycin Tablets	250 mg	30	65-404	AB	Zithromax	White, oval-shaped tablet	W 961	Wockhardt USA
64679-964-05	Azithromycin Tablets	500 mg	3 x 3	65-405	AB	Zithromax	White, oval-shaped tablet	W 964	Wockhardt USA
64679-964-01	Azithromycin Tablets	500 mg	30	65-405	AB	Zithromax	White, oval-shaped tablet	W 964	Wockhardt USA
64679-962-01	Azithromycin Tablets	600 mg	30	65-406	AB	Zithromax	White, oval-shaped tablet	W 962	Wockhardt USA
64679-965-01	Bethanechol Chloride Tablets	5 mg	100	40-532	AA	Urecholine	White, oval-shaped, scored tablet	W 965	Wockhardt USA
64679-966-01	Bethanechol Chloride Tablets	10 mg	100	40-533	AA	Urecholine	Pink, oval-shaped, scored tablet	W 966	Wockhardt USA
64679-967-01	Bethanechol Chloride Tablets	25 mg	100	40-534	AA	Urecholine	Light yellow, oval-shaped, scored tablet	W 967	Wockhardt USA
64679-968-01	Bethanechol Chloride Tablets	50 mg	100	40-518	AA	Urecholine	Yellow, oval-shaped, scored tablet	W 968	Wockhardt USA
64679-902-01	Captopril Tablets	12.5 mg	100	74-532	AB	Capoten	White, round, scored tablet	W 902	Wockhardt USA
64679-902-02	Captopril Tablets	12.5 mg	1000	74-532	AB	Capoten	White, round, scored tablet	W 902	Wockhardt USA
64679-903-01	Captopril Tablets	25 mg	100	74-532	AB	Capoten	White, round, double-scored tablet	W 903	Wockhardt USA
64679-903-02	Captopril Tablets	25 mg	1000	74-532	AB	Capoten	White, round, double-scored tablet	W 903	Wockhardt USA
64679-904-01	Captopril Tablets	50 mg	100	74-532	AB	Capoten	White, round, scored tablet	W 904	Wockhardt USA
64679-904-02	Captopril Tablets	50 mg	1000	74-532	AB	Capoten	White, round, scored tablet	W 904	Wockhardt USA
64679-905-01	Captopril Tablets	100 mg	100	74-532	AB	Capoten	White, round, scored tablet	W 905	Wockhardt USA
60432-129-16	Carbamazepine Suspension	100mg/5mL	450 mL	75-714	AB	Tegretol	Yellow-orange suspension with citrus-vanilla flavor	N/A	Morton Grove
64679-986-01	Cefotaxime for Injection	1 g	1	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA
64679-986-02	Cefotaxime for Injection	1 g	10	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA

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## Wockhardt USA & Morton Grove Pharmaceuticals Product List



### **NDC #**

### **Product Name**

### **Strength**

### **Pack Size**

### **ANDA #**

### **FDA Rating**

### **Color/Shape**

### **Imprint**

### **Product Line**

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-986-03	Cefotaxime for Injection	1 g	25	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA
64679-986-04	Cefotaxime for Injection	1 g	50	65-197	AP	Claforan	Dry, off-white to pale yellow crystalline powder in vial	NA	Wockhardt USA
64679-712-03	Cefprozil Tablets	250 mg	100	65-428	AB	Cefzil	White, film-coated, capsule-shaped tablet	W 712	Wockhardt USA
64679-713-01	Cefprozil Tablets	500 mg	50	65-428	AB	Cefzil	White, film-coated, capsule-shaped tablet	W 713	Wockhardt USA
64679-713-03	Cefprozil Tablets	500 mg	100	65-428	AB	Cefzil	White, film-coated, capsule-shaped tablet	W 713	Wockhardt USA
64679-701-01	Ceftriaxone for Injection	250 mg	1	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-701-02	Ceftriaxone for Injection	250 mg	10	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-701-03	Ceftriaxone for Injection	250 mg	25	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-702-01	Ceftriaxone for Injection	500 mg	1	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-702-02	Ceftriaxone for Injection	500 mg	10	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-983-01	Ceftriaxone for Injection	1 g	1	65-180	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-983-02	Ceftriaxone for Injection	1 g	10	65-180	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-703-02	Ceftriaxone for Injection	2 g	1	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-703-04	Ceftriaxone for Injection	2 g	10	65-391	AP	Rocephin	Sterile, crystalline powder in vial	NA	Wockhardt USA
64679-921-01	Cefuroxime Axetil Tablets	250 mg	20	65-166	AB	Ceftin	White, film-coated, round, unscored tablet	W 921	Wockhardt USA
64679-921-02	Cefuroxime Axetil Tablets	250 mg	60	65-166	AB	Ceftin	White, film-coated, round, unscored tablet	W 921	Wockhardt USA
64679-922-01	Cefuroxime Axetil Tablets	500 mg	20	65-166	AB	Ceftin	White, film-coated, capsule-shaped, unscored tablet	W 922	Wockhardt USA
64679-922-02	Cefuroxime Axetil Tablets	500 mg	60	65-166	AB	Ceftin	White, film-coated, capsule-shaped, unscored tablet	W 922	Wockhardt USA
60432-007-08	Cimetidine HCl Oral Solution	300mg/5mL	237 mL	74-757	AA	Tagamet	Clear to light orange solution with peach flavor	N/A	Morton Grove
64679-954-01	Clarithromycin Tablets	250 mg	60	65-266	AB	Biaxin	White, film-coated, oval-shaped tablet	W 949	Wockhardt USA
64679-949-01	Clarithromycin Tablets	500 mg	60	65-266	AB	Biaxin	White, film-coated, oval-shaped tablet	W 949	Wockhardt USA
60432-133-25	Clobetasol Topical Solution, USP	0.05%	25 mL	75-205	AT	Temovate	Colorless solution	N/A	Morton Grove
60432-133-50	Clobetasol Topical Solution, USP	0.05%	50 mL	75-205	AT	Temovate	Colorless solution	N/A	Morton Grove
60432-140-50	Cyclosporine Oral Solution	100mg/mL	50 mL	65-133	AB	Sandimmune	Clear yellow solution with olive flavor	N/A	Morton Grove
60432-466-08	Dexamethasone Elixir	0.5mg/5mL	237 mL	88-254	AA	Decadron	Clear red elixir with raspberry flavor	N/A	Morton Grove
60432-539-16	Dexchlorpheniramine Maleate Oral Solution	2mg/5mL	473 mL	88-251	AA	Polaramine	Red-orange syrup with orange flavor	N/A	Morton Grove
60432-651-04	Doxepin HCl Oral Solution	10mg/mL	118 mL	71-918	AA	Sinequan	Colorless solution with peppermint flavor	N/A	Morton Grove
64679-923-02	Enalapril Maleate Tablets	2.5 mg	100	75-483	AB	Vasotec	White, round, scored tablet	W 923	Wockhardt USA

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## Wockhardt USA & Morton Grove Pharmaceuticals Product List



### **NDC #**

### **Product Name**

### **Strength**

### **Pack Size**

### **ANDA #**

### **FDA Rating**

### **Compares To**

### **Color/Shape**

### **Imprint**

### **Product Line**

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-923-03	Enalapril Maleate Tablets	2.5 mg	1000	75-483	AB	Vasotec	White, round, scored tablet	W 923	Wockhardt USA
64679-924-02	Enalapril Maleate Tablets	5 mg	100	75-483	AB	Vasotec	White, round, scored tablet	W 924	Wockhardt USA
64679-924-03	Enalapril Maleate Tablets	5 mg	1000	75-483	AB	Vasotec	White, round, scored tablet	W 924	Wockhardt USA
64679-925-02	Enalapril Maleate Tablets	10 mg	100	75-483	AB	Vasotec	Light salmon, round, unscored tablet	W 925	Wockhardt USA
64679-925-03	Enalapril Maleate Tablets	10 mg	1000	75-483	AB	Vasotec	Light salmon, round, unscored tablet	W 925	Wockhardt USA
64679-926-02	Enalapril Maleate Tablets	20 mg	100	75-483	AB	Vasotec	Light beige, round, unscored tablet	W 926	Wockhardt USA
64679-926-03	Enalapril Maleate Tablets	20 mg	1000	75-483	AB	Vasotec	Light beige, round, unscored tablet	W 926	Wockhardt USA
60432-671-60	Erythromycin Topical Solution	2%	60 mL	62-825	AT	Eryderm	Colorless solution	N/A	Morton Grove
64679-936-01	Famotidine Tablets	20 mg	30	75-786	AB	Pepcid	Beige, barrel-shaped, unscored tablet	W 936	Wockhardt USA
64679-936-02	Famotidine Tablets	20 mg	100	75-786	AB	Pepcid	Beige, barrel-shaped, unscored tablet	W 936	Wockhardt USA
64679-936-03	Famotidine Tablets	20 mg	1000	75-786	AB	Pepcid	Beige, barrel-shaped, unscored tablet	W 936	Wockhardt USA
64679-937-01	Famotidine Tablets	40 mg	30	75-786	AB	Pepcid	White, barrel-shaped, unscored tablet	W 937	Wockhardt USA
64679-937-02	Famotidine Tablets	40 mg	100	75-786	AB	Pepcid	White, barrel-shaped, unscored tablet	W 937	Wockhardt USA
64679-937-03	Famotidine Tablets	40 mg	1000	75-786	AB	Pepcid	White, barrel-shaped, unscored tablet	W 937	Wockhardt USA
60432-162-04	Fluoxetine Oral Solution	20mg/5mL	118 mL	75-514	AA	Prozac	Colorless/pale yellow solution with slight mint flavor	N/A	Morton Grove
64679-729-01	Fosphenytoin Sodium Injection	50 mg PE/mL	2 mL x 25	78-137	AP	Cerebyx	(100mg PE in 2mL; PE=phenytoin sodium equivalents)	N/A	Wockhardt USA
64679-730-01	Fosphenytoin Sodium Injection	50 mg PE/mL	10 mL x 10	78-137	AP	Cerebyx	Colorless/pale yellow, clear solution in vial (500mg PE in 10mL; PE=phenytoin sodium equivalents)	N/A	Wockhardt USA
60432-613-60	Furosemide Oral Solution	10mg/mL	60 mL	70-655	AA	Lasisix	Yellow solution with orange flavor	N/A	Morton Grove
60432-613-04	Furosemide Oral Solution	10mg/ml	118 mL	70-655	AA	Lasisix	Yellow solution with orange flavor	N/A	Morton Grove
60432-038-16	Generlac Solution	10gm/15mL	473 mL	74-603	AA	Cephulac	Colorless to yellow solution with no flavor	N/A	Morton Grove
60432-038-64	Generlac Solution	10gm/15mL	1892 mL	74-603	AA	Cephulac	Colorless to yellow solution with no flavor	N/A	Morton Grove
64679-662-01	Granisetron HCl Injection	0.1 mg/mL	1 mL x 5	78-566	AP	Kytril	Clear, colorless solution in vial	N/A	Wockhardt USA
60432-455-16	Hydrocodone and Homatropine Syrup	5/1.5mg per 5mL	473 mL	88-008	AA	Hycodan	Red syrup with cherry flavor	N/A	Morton Grove
60432-150-04	Hydroxyzine HCl Syrup	10mg/5mL	118 mL	87-294	AA	Atarax	Colorless syrup with peppermint flavor	N/A	Wockhardt USA
60432-150-16	Hydroxyzine HCl Syrup	10mg/5mL	473 mL	87-294	AA	Atarax	Colorless syrup with peppermint flavor	N/A	Morton Grove
64679-757-03	Ketorolac Tromethamine Injection	15mg/mL	1 mL x 1	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-757-02	Ketorolac Tromethamine Injection	15mg/mL	1 mL x 10	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-757-01	Ketorolac Tromethamine Injection	15mg/mL	1 mL x 25	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA



# Wockhardt USA & Morton Grove Pharmaceuticals Product List



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NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-758-04	Ketorolac Tromethamine Injection	30mg/mL	1 mL x 10	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-01	Ketorolac Tromethamine Injection	30mg/mL	1 mL x 25	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-05	Ketorolac Tromethamine Injection	30mg/mL	2 mL x 1	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-06	Ketorolac Tromethamine Injection	30mg/mL	2 mL x 10	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-758-02	Ketorolac Tromethamine Injection	30mg/mL	2 mL x 25	77-942	AP	Toradol	Clear, colorless solution in vial	N/A	Wockhardt USA
60432-037-08	Lactulose Solution	10gm/15mL	237 mL	74-602	AA	Chronulac	Colorless to pale yellow solution with no flavor	N/A	Morton Grove
60432-037-32	Lactulose Solution	10gm/15mL	946 mL	74-602	AA	Chronulac	Colorless to pale yellow solution with no flavor	N/A	Morton Grove
60432-464-00	Lidocaine HCl Oral Solution	2%	100 mL	87-872	AT	Xylocaine	Colorless to pale yellow solution with cherry flavor	N/A	Morton Grove
60432-465-50	Lidocaine HCL Topical Solution	4%	50 mL	87-881	AT	Xylocaine	Colorless solution	N/A	Morton Grove
60432-833-60	Lindane Lotion	1%	60 mL	88-190	AT	Kwell	White to pale yellow lotion	N/A	Morton Grove
60432-834-60	Lindane Shampoo	1%	60 mL	88-191	AT	Kwell	Pale yellow shampoo	N/A	Morton Grove
64679-927-01	Lisinopril Tablets	2.5 mg	100	78-402	AB	Zestril	White to off-white, round, unscored tablet	W	Wockhardt USA
64679-927-05	Lisinopril Tablets	2.5 mg	500	78-402	AB	Zestril	White to off-white, round, unscored tablet	W	Wockhardt USA
64679-928-01	Lisinopril Tablets	5 mg	100	78-402	AB	Zestril	White to off-white, round, scored tablet	W 928	Wockhardt USA
64679-928-06	Lisinopril Tablets	5 mg	1000	78-402	AB	Zestril	White to off-white, round, scored tablet	W 928	Wockhardt USA
64679-929-01	Lisinopril Tablets	10 mg	100	78-402	AB	Zestril	White to off-white, round, unscored tablet	W 929	Wockhardt USA
64679-929-06	Lisinopril Tablets	10 mg	1000	78-402	AB	Zestril	White to off-white, round, unscored tablet	W 929	Wockhardt USA
64679-941-01	Lisinopril Tablets	20 mg	100	78-402	AB	Zestril	Light yellow, round, unscored tablet	W 941	Wockhardt USA
64679-941-06	Lisinopril Tablets	20 mg	1000	78-402	AB	Zestril	Light yellow, round, unscored tablet	W 941	Wockhardt USA
64679-953-01	Lisinopril Tablets	30 mg	100	78-402	AB	Zestril	Light red, round, unscored tablet	W 953	Wockhardt USA
64679-953-05	Lisinopril Tablets	30 mg	500	78-402	AB	Zestril	Light red, round, unscored tablet	W 953	Wockhardt USA
64679-942-01	Lisinopril Tablets	40 mg	100	78-402	AB	Zestril	Light brown, round, unscored tablet	W 942	Wockhardt USA
64679-942-02	Lisinopril Tablets	40 mg	1000	78-402	AB	Zestril	Light brown, round, unscored tablet	W 942	Wockhardt USA
60432-616-16	Lithium Citrate Syrup	300mg/5mL	473 mL	70-755	AA	Cibalith-S	Colorless syrup with raspberry flavor	N/A	Morton Grove
60432-126-08	Megestrol Acetate Oral Suspension	40mg/mL	237 mL	76-721	AB	Megace	Creamy white suspension with lemon-lime flavor	N/A	Morton Grove
60432-126-16	Megestrol Acetate Oral Suspension	40mg/mL	473 mL	76-721	AB	Megace	Creamy white suspension with lemon-lime flavor	N/A	Morton Grove
60432-622-16	Meloxicam HCl Oral Solution	5mg/5mL	473 mL	74-703	AA	Reglan	Orange syrup with butterscotch flavor	N/A	Morton Grove
60432-482-16	Myphene DX Cough Syrup (Pseudoephedrine; Dextronethet: Bromphen) 5mL	30/10/2mg per 5mL	473 mL	88-811	AA	Dimetane-DX	Clear; light pink syrup with butterscotch flavor	N/A	Morton Grove



# Wockhardt USA & Morton Grove Pharmaceuticals Product List



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NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
60432-537-60	Nystatin Oral Suspension	100,000 units/mL	60 mL	62-512	AA	Mycostatin	Light creamy yellow suspension with fruit flavor	N/A	Morton Grove
60432-537-16	Nystatin Oral Suspension	100,000 units/mL	473 mL	62-512	AA	Mycostatin	Light creamy yellow suspension with fruit flavor	N/A	Morton Grove
64679-726-01	Ondansetron Injection	2mg/mL	2 mL x 5	77-716	AP	Zofran	Clear, colorless solution in vial	N/A	Wockhardt USA
64679-727-01	Ondansetron Injection	2mg/mL	20 mL x 1	77-757	AP	Zofran	Clear, colorless solution in vial	N/A	Wockhardt USA
60432-092-16	Oxybutynin Chloride Syrup	5mg/5mL	473 mL	74-868	AA	Ditropan	Light aqua syrup with raspberry flavor	N/A	Morton Grove
60432-131-08	Phenytoin Oral Suspension	125mg/5mL	237 mL	40-420	AB	Dilantin	Orange suspension with orange+vanilla flavor	N/A	Morton Grove
64679-720-01	Phenytoin Sodium Extended Capsules	100 mg	100	40-732	AB	Dilantin	Orange body and cap	W 720	Wockhardt USA
64679-720-02	Phenytoin Sodium Extended Capsules	100 mg	1000	40-732	AB	Dilantin	Orange body and cap	W 720	Wockhardt USA
60432-212-08	Prednisolone Sodium Phosphate Oral Solution	15mg/5mL	237 mL	76-895	AA	Orapred	Red solution with cherry flavor	N/A	Morton Grove
60432-608-04	Promethazine Syrup Plain	6.25mg/5mL	118 mL	87-953	AA	Phenergan	Green syrup with tropical fruit flavor	N/A	Morton Grove
60432-608-16	Promethazine Syrup Plain	6.25mg/5mL	473 mL	87-953	AA	Phenergan	Green syrup with tropical fruit flavor	N/A	Morton Grove
60432-606-16	Promethazine w/Codine Cough Syrup	6.25/10mg per 5mL	473 mL	88-875	AA	Phenergan w/Codine	Clear purple syrup with raspberry flavor	N/A	Morton Grove
60432-604-04	Promethazine w/D/M Cough Syrup	6.25/15mg per 5mL	118 mL	88-864	AA	Phenergan w/D/M	Clear yellow syrup with pineapple flavor	N/A	Morton Grove
60432-604-16	Promethazine w/D/M Cough Syrup	6.25/15mg per 5mL	473 mL	88-864	AA	Phenergan w/D/M	Clear yellow syrup with pineapple flavor	N/A	Morton Grove
64679-906-01	Ranitidine Tablets	150 mg	60	75-208	AB	Zantac	White, film coated, six-sided, unscored, tablet	W 906	Wockhardt USA
64679-906-06	Ranitidine Tablets	150 mg	100	75-208	AB	Zantac	White, film coated, six-sided, unscored, tablet	W 906	Wockhardt USA
64679-906-03	Ranitidine Tablets	150 mg	500	75-208	AB	Zantac	White, film coated, six-sided, unscored, tablet	W 906	Wockhardt USA
64679-907-01	Ranitidine Tablets	300 mg	30	75-208	AB	Zantac	White, film coated, capsule-shaped, unscored, tablet	W 907	Wockhardt USA
64679-907-04	Ranitidine Tablets	300 mg	100	75-208	AB	Zantac	White, film coated, capsule-shaped, unscored, tablet	W 907	Wockhardt USA
64679-907-02	Ranitidine Tablets	300 mg	250	75-208	AB	Zantac	White, film coated, capsule-shaped, unscored, tablet	W 907	Wockhardt USA
60432-528-04	Selenium Sulfide Lotion	2.5%	118 mL	88-228	AT	Selsun	Beige lotion	N/A	Morton Grove
64679-752-01	Serritaline HCl Tablets	50 mg	100	78-403	AB	Zoloft	Blue, film-coated, capsule-shaped, scored tablet	W 752	Wockhardt USA
64679-752-04	Serritaline HCl Tablets	50 mg	500	78-403	AB	Zoloft	Blue, film-coated, capsule-shaped, scored tablet	W 752	Wockhardt USA
64679-752-07	Serritaline HCl Tablets	50 mg	1000	78-403	AB	Zoloft	Blue, film-coated, capsule-shaped, scored tablet	W 752	Wockhardt USA
64679-753-01	Serritaline HCl Tablets	100 mg	100	78-403	AB	Zoloft	Yellow, film-coated, capsule-shaped, scored tablet	W 753	Wockhardt USA
64679-753-04	Serritaline HCl Tablets	100 mg	500	78-403	AB	Zoloft	Yellow, film-coated, capsule-shaped, scored tablet	W 753	Wockhardt USA
64679-753-07	Serritaline HCl Tablets	100 mg	1000	78-403	AB	Zoloft	Yellow, film-coated, capsule-shaped, scored tablet	W 753	Wockhardt USA
64679-209-01	Terbinafine HCl Tablets	250 mg	30	77-533	AB	Lamisil	White, round, unscored tablet	IG 209	Wockhardt USA



## Wockhardt USA & Morton Grove Pharmaceuticals Product List



### NDC #

### Product Name

### Strength

### Pack Size

### ANDA #

### FDA Rating

### Compares To

### Color/Shape

### Imprint

### Product Line

NDC #	Product Name	Strength	Pack Size	ANDA #	FDA Rating	Compares To	Color/Shape	Imprint	Product Line
64679-209-02	Terbinafine HCl Tablets	250 mg	100	77-533	AB	Lamisil	White, round, unscored tablet	IG 209	Wockhardt USA
60432-560-60	Triamcinolone Acetonide Lotion	0.025%	60 mL	88-450	AT	Kenalog	Creamy white lotion	N/A	Morton Grove
60432-561-60	Triamcinolone Acetonide Lotion	0.1%	60 mL	88-451	AT	Kenalog	Creamy white lotion	N/A	Morton Grove
60432-621-16	Valproic Acid Syrup	250mg/5mL	473 mL	70-868	AA	Depakene	Red syrup with cherry flavor	N/A	Morton Grove
64679-714-01	Zolpidem Tartrate Tablets	5 mg	100	78-426	AB	Ambien	Pink, film-coated, capsule-shaped tablet	W 714	Wockhardt USA
64679-714-04	Zolpidem Tartrate Tablets	5 mg	500	78-426	AB	Ambien	Pink, film-coated, capsule-shaped tablet	W 714	Wockhardt USA
64679-715-01	Zolpidem Tartrate Tablets	10 mg	100	78-426	AB	Ambien	White, film-coated, capsule-shaped tablet	W 715	Wockhardt USA
64679-715-04	Zolpidem Tartrate Tablets	10 mg	500	78-426	AB	Ambien	White, film-coated, capsule-shaped tablet	W 715	Wockhardt USA
64679-945-01	Zonisamide Capsules	25 mg	100	77-636	AB	Zonegran	White, opaque body and white opaque cap	W 945	Wockhardt USA
64679-946-01	Zonisamide Capsules	50 mg	100	77-636	AB	Zonegran	White, opaque body and grey opaque cap	W 946	Wockhardt USA
64679-990-01	Zonisamide Capsules	100 mg	100	77-636	AB	Zonegran	White opaque body and orange opaque cap	W 990	Wockhardt USA

# EXHIBIT 3

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## MORTON GROVE PHARMACEUTICALS

[Information DOWNLOADS](#)

### Commitment to Public Health and Safety

*Points of View on Lindane:*

Morton Grove Pharmaceuticals, Inc. (MGP) is a specialty pharmaceutical company headquartered in Illinois, and is one of the leading manufacturers of generic prescription oral liquid and topical medications in the U.S. The company employs more than 260 professionals in the areas of research and development, compliance, regulatory affairs, manufacturing, distribution, and sales. As the sole U.S. manufacturer of lindane lotion and lindane shampoo, MGP has worked with the Food and Drug Administration (FDA) to advance the safety and usefulness of this second-line medication.

[FOOD AND DRUG ADMINISTRATION](#)  
[ENVIRONMENTAL PROTECTION AGENCY](#)  
[CENTERS FOR DISEASE CONTROL AND PREVENTION](#)  
[MEDICAL & SCIENTIFIC OPINIONS](#)

A portfolio of therapies that benefit public health

**A strong commitment to quality manufacturing and research and development has enabled MGP to help lead the industry in providing the healthcare community and the public with affordable generic liquid prescription medications.**

More than 65 different prescription therapies are owned and developed by MGP—the majority are cost-saving generics

Core therapeutics are manufactured at MGP's 125,000 square foot, state-of-the-art facility located in Morton Grove, Illinois, with another research facility in Vernon Hills, Illinois

Research and development efforts are supported by the innovation of more than 30 R&D scientists and more than 260 employees overall

MGP therapies are used in many different areas of medicine

Allergy	Infectious disease
Cardiology	Internal medicine
Dermatology	Neurology
Gastroenterology	Pediatric psychiatry
Immunology	Transplant medicine

Continued investments in lindane safety

MGP recognizes the public health need to preserve lindane as a second-line therapy and has already taken important measures to minimize the risk for product misuse. In consultation with regulatory experts, MGP has also initiated an extensive and rigorous lindane clinical research program. This ongoing investment is designed to further enhance the benefit-safety balance of lindane medications.



Morton Grove Pharmaceuticals, Inc.

[Commitment to Public Health and Safety](#) | [Lindane Prescribing Information](#) | [FDA Information on Lindane](#)

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## Lindane Prescribing INFORMATION

[Information DOWNLOADS](#)

### Lindane Lotion for Scabies

[Package insert \(pdf\)](#)

[Medication guide \(pdf\)](#)

*Points of View on Lindane:*

[FOOD AND DRUG](#)

[ADMINISTRATION](#)

[ENVIRONMENTAL](#)

[PROTECTION AGENCY](#)

[CENTERS FOR DISEASE](#)

[CONTROL AND PREVENTION](#)

[MEDICAL & SCIENTIFIC](#)

[OPINIONS](#)

### Lindane Shampoo for Lice

[Package insert \(pdf\)](#)

[Medication guide \(pdf\)](#)

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# LINDANE LOTION, USP 1% Rx only

## **WARNINGS:**

Lindane Lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies. (See INDICATIONS AND USAGE.)

## **Neurologic Toxicity**

Seizures and deaths have been reported following Lindane Lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane Lotion should be used with caution for infants, children, the elderly, and individuals with other skin conditions (e.g., atopic dermatitis, psoriasis) and in those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

## **Contraindications**

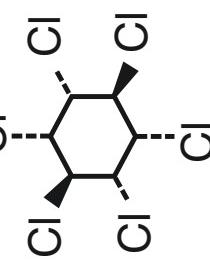
Lindane Lotion is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

## **Proper Use**

Instruct patients on the proper use of Lindane Lotion, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of scabies and is not necessarily an indication for retreatment with Lindane Lotion. (See DOSAGE AND ADMINISTRATION.)

## **DESCRIPTION**

Lindane Lotion, USP 1%, is an ectoparasiticide and ovicide. In addition to the active ingredient, lindane, it contains 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylparaben, purified water, stearic acid and trolamine to form a lotion. The pH range is between 6.5 and 8.5. Lindane is the gamma isomer of 1,2,3,4,5-hexachlorocyclohexane having the following structural formula:



C<sub>6</sub>H<sub>6</sub>Cl<sub>6</sub>

## **CLINICAL PHARMACOLOGY**

Lindane Lotion, USP 1%, is an ectoparasiticide and ovicide effective against *Sarcoptes scabiei* (scabies). Lindane exerts its parasiticidal action by being directly absorbed into the parasites and their ova. Feldmann and Maibach<sup>1</sup> reported approximately 10% systemic absorption of a lindane acetone solution when applied to the forearm of human subjects and left in place for 24 hours. This vehicle was different from the approved product and the percutaneous penetration of lindane is dependent on the vehicle. Therefore, the clinical significance of these observations is unknown. Dale, et al<sup>2</sup> reported a blood level of 290 ng/mL associated with convulsions following the accidental ingestion of a lindane-containing product. Ginsburg<sup>3</sup> found the greatest peak blood level of 64 ng/mL, 6 hours after total body application of Lindane Lotion in 1 of 8 non-scabetic pediatric patients. The half-life in blood was determined to be approximately 18 hours.

Data available in the literature suggest that lindane has a rapid distribution phase followed by a longer β-elimination phase.<sup>1,2,3</sup>

## **INDICATIONS AND USAGE**

Lindane Lotion is indicated for the treatment of scabies (infestations of *Sarcoptes scabiei*) only in patients who:

1. cannot tolerate other approved therapies, or
2. have failed treatment with other approved therapies.

Lindane Lotion should be used in the context of an overall scabies management program that includes:

- Microscopic evaluation of skin scrapings to confirm the diagnosis.
- Evaluation and treatment of sexual contacts simultaneously. Sexual contacts should be prescribed Lindane Lotion only if they either have failed to respond to adequate doses of other approved therapies or are intolerant of other approved therapies.
- Washing of all recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels in very hot water or dry-cleaned.

Caregivers applying this product to patients should wear gloves less permeable to Lindane, such as nitrile, latex with neoprene, or sheer vinyl, and thoroughly clean hands after application. Natural latex gloves should be avoided because they are more permeable to Lindane.

Lindane Lotion does not prevent infestation or reinfection and should not be used to ward off a possible infestation.

## **CONTRAINdications**

Lindane Lotion is contraindicated for premature infants because their skin may be more permeable than that of full term infants

and their liver enzymes may not be sufficiently developed to metabolize Lindane.

Lindane Lotion is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.

Lindane Lotion is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

#### **WARNINGS (See boxed WARNINGS.)**

Seizures and deaths have been reported following Lindane Lotion's use with repeat or prolonged application, but also in rare cases following a single application reportedly used according to directions. It is not known how soon after application of a single dose of Lindane Lotion that a second dose of Lindane Lotion can be safely applied.

There have been cases of adverse events reported for Lindane Lotion and Lindane Shampoo in which a serious outcome (hospitalization, disability or death) has occurred.<sup>4</sup> In approximately 20% of the total reported cases, Lindane Lotion and Shampoo were reported to have been used according to the labeled directions. Of these cases, thirteen deaths were reported, many cases which were remote from the time of actual Lindane use. Lindane toxicity, verified by autopsy was the cause of one infant's death, was the cause of death reported for an adult who ingested it orally in a successful suicide. The direct causes of death for the other cases were attributed to reasons other than Lindane. Most of these adverse events occurred with Lindane Lotion.

Infants, children, the elderly, and individuals with other skin conditions and those who weigh < 110 lbs (50 kg) may be at greater risk of serious neurotoxicity. (See Pediatric Use and Geriatric Use.) Animal studies have shown increased susceptibility to neurologic adverse events in younger animals. Children have a larger body surface area to volume ratio that may result in a proportionately larger systemic exposure.

Careful consideration should be given before prescribing Lindane Lotion to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold. (See PRECAUTIONS: Drug Interactions.)

Patients should be instructed on proper use of Lindane Lotion, especially the amount to apply, how long to leave the lotion on, and the need to avoid retreatment. Patients should be informed that itching may occur, and even worsen, after the successful killing of scabies. Repeat treatment is usually not necessary.

A Lindane Lotion Medication Guide must be given to the patient each time Lindane Lotion is dispensed, as required by law.

## **PRECAUTIONS**

**General:** Care should be taken to avoid contact with the eyes. If such contact occurs, eyes should be immediately flushed with water. If irritation or sensitization occurs, the patient should be advised to consult a physician.

### **Information for Patients (and Caregivers):**

- **This product can be poisonous if misused.**

- **Other important information is found in the Medication Guide, which by law, must be dispensed with Lindane Lotion.**

- If someone other than the patient will be applying Lindane Lotion to the patient, they should wear less permeable gloves such as nitrite, latex with neoprene, or sheer vinyl, and thoroughly clean their hands after application. Natural latex gloves should be avoided because they are more permeable to lindane.

- If the person applying Lindane Lotion could be pregnant, contact with Lindane Lotion should be avoided as much as possible.

- If the patient could be pregnant, other treatments may be preferable.

- Lindane Lotion should be used for scabies only.

- The skin should be clean and without any other lotion, cream, or oil on it. Oils can make the Lindane Lotion go through the skin faster and possibly increase the risk of neurotoxicity (e.g., seizures).

- Wait at least 1 hour after bathing or showering before putting Lindane Lotion on the skin. Wet or warm skin can make the Lindane Lotion go through skin faster.

- Information for Use:

- Shake Lindane Lotion well.

- Put Lindane Lotion under fingernails after trimming the fingernails short, because scabies are very likely to remain there. A toothbrush can be used to apply the Lindane Lotion under the fingernails. Immediately after use, the toothbrush should be wrapped in paper and thrown away. Use of the same brush in the mouth could lead to poisoning.

- Use only a single application, applied as a very thin layer over all skin from the neck down.

- Close the bottle with the leftover Lindane Lotion and immediately throw it away in a trash can out of the reach of children. Do not use any covering over the applied Lindane Lotion that does not breathe, like diapers with plastic lining, plastic clothes, tight clothes, or blankets.

- Wash the Lindane Lotion completely off after 8 to 12 hours. Never leave Lindane Lotion on the skin for more than 12 hours. Warm, but not hot water can be used. Lindane Lotion will not kill any more scabies after 8 to 12 hours, but may cause serious

health problems.

- Keep Lindane Lotion away from mouth and eyes. If contact with eyes occurs, immediately flush eyes with water. Do not use if you have open wounds, cuts or sores that are present, unless specifically directed by the prescribing physician.
- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.

- The patient may still itch after using Lindane Lotion. This does not mean the medicine did not work. Even after all the scabies (bugs) are dead, they can still make the skin itch for a few weeks. Lindane Lotion sometimes makes this itch even worse. Other treatments can be used to soothe the itch. Do not use more Lindane Lotion.
- The patient should contact the physician with any questions or concerns about his or her condition or use of the Lindane Lotion.

**Drug Interactions:** Oils may enhance absorption of Lindane, therefore, patients or caregivers applying Lindane Lotion should be warned about simultaneous use of creams, ointments, or oils. In addition, there are many drugs that may lower the seizure threshold, and Lindane Lotion should be prescribed with caution in patients taking these medications. Drugs that may lower the seizure threshold include, but are not limited to the following:

- Antipsychotics
- Antidepressants
- Theophylline
- Cyclosporine, mycophenolate mofetil, tacrolimus capsules
- Penicillins, imipenem, quinolone antibiotics
- Chloroquine sulfate, pyrimethamine
- Isoniazid
- Meperidine
- Radiographic contrast agents
- Centrally active anticholinesterases
- Methocarbamol

**Carcinogenesis, Mutagenesis, and Fertility:** Although no studies have been conducted with Lindane Lotion, numerous long-term feeding studies have been conducted in mice and rats to evaluate the carcinogenic potential of the technical grade of hexachlorocyclohexane as well as the alpha, beta, gamma (lindane) and delta isomers. Both oral and topical applications have been evaluated. Increased incidences of neoplasms were not clearly related to administration of lindane. The results of

mutagenicity tests in bacteria do not indicate that lindane is mutagenic. Lindane did not cause sister chromatid exchange in an *in vivo* assay. The number of spermatids in the testes of rats 2 weeks after oral administration of a single dose of 30 mg/kg body weight (12 times the estimated human exposure for scabies on a body surface area comparison and assuming 50% rat oral bioavailability and 10% human bioavailability) was significantly reduced compared to the control rats.

**Pregnancy Category C.** All pregnancies have a risk of birth defect, loss, or other adverse event regardless of drug exposure. Predictions of fetal risk from drug exposure rely heavily on animal data. However, animal studies may fail to predict effects in humans or may overstate such risks. Even if human data are available, the data may not be sufficient to determine whether there is an increased risk to the fetus, and individual reports of adverse outcomes in pregnancy in association with a drug may not reflect a causal relationship.

Lindane Lotion should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Lotion in pregnant women. There are no known maternal or fetal health risks if the scabies is not treated. Lindane is lipophilic and accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures to lindane during pregnancy. The relationship of the maternal exposures to the fetal outcome is unknown.

Animal data suggest that lindane exposure of the fetus may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug.

Data: When rats received lindane in the diet from day 6 of gestation through day 10 of lactation, reduced pup survival, decreased pup weight and decreased weight gains during lactation, increased motor activity and decreased motor activity habituation were seen in pups at 5.6 mg/kg (2 times the estimated human exposure) but not at 1.2 mg/kg. An increased number of stillborn pups was seen at 8 mg/kg, and increased pup mortality was seen at 5.6 mg/kg. No gross abnormalities were seen in this study or in a study in which rabbits received up to 20 mg/kg lindane by gavage on gestation day 6-18 (up to 10 times the human exposure on a body surface area comparison and assuming 50% rabbit oral bioavailability and 10% human bioavailability).

**Nursing Mothers:** Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding when Lindane Lotion is applied topically to the chest area. Nursing mothers who require treatment with Lindane Lotion should be advised of the potential risks and be counseled to avoid large areas of skin-to-skin contact with the infant while Lindane Lotion is applied, as well as to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use.

**Pediatric Use:** Animal data demonstrated increased risk of adverse events in the young across species. Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Lotion is applied to the body. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver. Lindane Lotion should be used with extreme caution in patients who weigh less than approximately 110 lbs (50 kg) and especially in infants. Lindane Lotion is indicated only for the treatment of scabies; patients with lice should use Lindane Shampoo according to the labeled instructions.

**Geriatric Use:** There have been no studies of Lindane Lotion in the elderly. There are four postmarketing reports of deaths in elderly patients who were treated for scabies with Lindane Lotion. Two patients died within 24 hours of Lindane Lotion application and the third patient died 41 days after application of Lindane Lotion, having suffered a seizure on the day of death. A fourth patient died of an unreported cause of death on the same day that Lindane Lotion treatment for scabies was administered.

#### **ADVERSE REACTIONS**

Lindane Lotion has been reported to cause central nervous system stimulation ranging from dizziness to seizures. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Lotion was used according to directions. Irritant dermatitis from contact with this product has also been reported. (See WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION.)

**Postmarketing Experience:** The following adverse reactions reflect additional postmarketing experience of Lindane Lotion. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria. The relationship of some of these events to Lindane therapy is unknown.

#### **OVERDOSAGE**

Contact the closest Poison Control Center in the event of suspected overdosage with Lindane Lotion.

If accidental ingestion occurs, prompt gastric lavage should be instituted. However, since oils enhance absorption, saline cathartics for intestinal evacuation should be given rather than oil laxatives. If central nervous system (CNS) manifestations occur they may be antagonized by the administration of pentobarbital, phenobarbital, or diazepam.

#### **DOSAGE AND ADMINISTRATION**

Apply a thin layer of Lindane Lotion over all skin from the neck down. One ounce is sufficient for an average adult. Do not prescribe more than 2 ounces for larger adults. Apply only once. Wash off in 8 to 12 hours. Do not retreat. (See boxed WARNINGS.)

Patients should be provided specific information on use of product. (See PRECAUTIONS: Information for Patients and the Medication Guide.) Patients should be instructed on proper use of Lindane Lotion, especially the amount to apply, how long to leave on and the need to avoid retreatment. Patients should be informed that itching occurs after the successful killing of scabies (lice) and continued itching is not necessarily an indication for retreatment with Lindane Lotion.

A **Lindane Lotion Medication Guide** must be given to the patient each time Lindane Lotion is dispensed, as required by law. The Lindane Lotion Medication Guide is an important part of the risk management program for the patient.

## HOW SUPPLIED

Lindane Lotion, USP 1% is supplied in patient-size 2 fl oz (60 mL) bottles.

SHAKE WELL BEFORE USING

**Store at controlled room temperature, 15 ° - 30 °C (59 ° - 86 °F) [see USP].**

## REFERENCES

1. Feldmann, R.J. and Maibach, H.I., *Toxicol. Applied Pharmacol.*, 28:126, 1974.
2. Dale, W.E., Curly, A. and Cuetos, C. *Life Sci* 5:47, 1966.
3. Ginsburg, C.M., et al., *J. Pediatr.* 91:6, 998-1000, 1977.
4. FDA AERS database search, January 2003

## Rx Only

Product No.: 8546

**Manufactured By:** Morton Grove Pharmaceuticals, Inc.

Morton Grove, IL 60053

**Distributed By:** Alliant Pharmaceuticals, Inc. Alpharetta, GA 30004

**PHARMACIST—PATIENT MEDICATION GUIDE PROVIDED BELOW**

## MEDICATION GUIDE

**Lindane (LIHN-dane) Lotion, USP 1%**

**You must read and follow all instructions before using Lindane Lotion.** Read the information you get every time you

or a family member get Lindane Lotion. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Lindane Lotion, ask your doctor or pharmacist.

## **What is the most important information I should know about Lindane Lotion?**

**Lindane Lotion is a poison if you do not use it the right way.** Lindane Lotion goes through your skin and may affect your brain and nerves. Lindane Lotion can cause seizures, also called convulsions, “fits” or epilepsy.

- Seizures and death can happen in people who use Lindane Lotion too much or too often.
- Seizures can happen in some people even if they use Lindane Lotion exactly as directed.

## **If you or a family member has a seizure while using Lindane Lotion, get emergency help right away.**

- Do not use Lindane Lotion unless:
  - You have scabies and were treated with another medicine that did not work for you, or
  - You cannot use other safer medicines to treat your scabies.
- Do not use Lindane Lotion more than 1 time to treat an attack of scabies. Do not use Lindane Lotion to treat a second attack of scabies that comes soon after the first episode. Using it more than 1 time can cause seizures and death. No one knows a safe time to reuse Lindane Lotion. Even if you still itch after using Lindane Lotion, do not use more or use it again. Scabies (bugs) can make your skin itch for a few weeks even after all of the bugs are dead.
- Do not use more Lindane Lotion than your doctor tells you.
- Do not keep Lindane Lotion on your skin for more than 8 to 12 hours.
- Do not put Lindane Lotion in your mouth because it is a poison if taken by mouth. If you get Lindane Lotion in your mouth or swallow Lindane Lotion, call your area Poison Control Center right away and get emergency help.

## **What is Lindane Lotion?**

Lindane Lotion is a medicine that is used to treat scabies. It kills scabies and their eggs. Scabies are very small bugs that crawl under your skin, lay eggs, and cause severe itching. Lindane Lotion goes through your skin and kills the scabies and their eggs. Lindane Lotion is used only after safer medicines have not made your scabies go away. The only time Lindane Lotion is used first is when someone cannot use safer medicines, which may include permethrin and crotamiton.

**Lindane Lotion is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds, use**

**Lindane Lotion only if your doctor thinks it is really needed. People who weigh less than 110 pounds and the elderly have higher chances for side effects because more lindane may go through their skin.**

### **Who should not use Lindane Lotion?**

#### **Do not use Lindane Lotion:**

- if you do not have scabies. Lindane Lotion does not stop you from getting scabies. Lindane Lotion only kills the scabies you already have.
- if you have or have ever had seizures, also called convulsions, “fits” or epilepsy, especially if they have been hard to control.
- if you used Lindane Lotion in the past few months. You should see your doctor if you think you need another treatment.
- unless it is the only medicine you can use for scabies.
- if you had a bad reaction to Lindane Lotion before. **Do not use Lindane Lotion again.**
- if you have open sores or crusted (scabby) sores on your skin, or lots of broken skin.
- if you have head or body lice. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Lotion or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Lotion.
- if you need to treat a premature or young baby. More lindane can go through the skin of babies and go to their brains where it can harm them.
- while you are breast-feeding. Lindane Lotion can get in your milk and be fed to your baby. Lindane Lotion on your skin can also go to your baby. Your baby may get sick. Ask your doctor for a safer medicine. If you use Lindane Lotion, pump your breast milk and throw away the milk for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk you stored from before you used Lindane Lotion.

#### **Tell your doctor if you:**

- used Lindane Lotion in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Lotion may cause seizures even if you never had them before.
- are pregnant. Lindane Lotion can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Lotion only if needed.

- have a sexual partner. Your partner should get checked and treated for scabies so they don't give them back to you. Don't share your Lindane Lotion with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Lotion. Especially, tell your doctor if you take medicines called sedatives (drugs to help you sleep).

## How do I use Lindane Lotion?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Lotion on another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. **Do not use natural latex gloves because more lindane can go through that kind of glove. Wash your hands well when you are done.**

- Make sure your skin is clean and does not have any other lotion, cream, or oil on it. Oils can make Lindane Lotion go through your skin faster and may increase the risk of seizures.
- Wait for at least 1 hour after bathing or showering before you put Lindane Lotion on your skin. Wet or warm skin can make the Lindane Lotion go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Lotion well.
- Put Lindane Lotion under your fingernails, because the scabies really like to stay there. Trim your fingernails short. Use a toothbrush to get the Lindane Lotion under your fingernails. Wrap this toothbrush in paper and throw this toothbrush away. Do not use it in your mouth.
- Put a very thin layer of the Lindane Lotion on your skin from the neck down. You may have some Lindane Lotion left in the bottle.
- Do not cover over the Lindane Lotion on your skin with anything that does not breathe, like diapers with a plastic lining, plastic clothes, tight clothes, or blankets.
- Close the bottle with the leftover Lindane Lotion and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- Wash the Lindane Lotion off your skin after 8 to 12 hours. You must wash the Lindane Lotion off your body completely.

Use warm, but not hot water. Lindane Lotion will not kill any more scabies after 8 to 12 hours. After 8 to 12 hours, Lindane Lotion can cause serious health problems, such as seizures and death.

After you wash off the Lindane Lotion:

- All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Lotion again. If you think you need to use it again, you must check with your doctor to find out when it is most safe.

You may still itch after you use Lindane Lotion. **This does not mean you need more Lindane Lotion.** Even after all the scabies bugs are dead, they can still make your skin itch for a few weeks. Lindane Lotion sometimes makes this itch even worse. Talk to your doctor about things you can do to soothe the itch.

### **What should I avoid while using Lindane Lotion?**

- Do not get Lindane Lotion in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not let your skin touch other people's skin while you have Lindane Lotion on. Make sure your skin does not touch your baby or small child.
- If you are pregnant, do not use Lindane Lotion, or apply Lindane Lotion to others unless it is needed and you have talked to your doctor about using it. See the special glove advice below if you have to put Lindane Lotion on others.
- Do not use oils on your skin or hair just before or after using Lindane Lotion. Oils include skin lotions and moisturizers, and oil-based hair products and conditioners.
- Do not get Lindane Lotion on your hands if you are putting it on someone else. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.

### **What are the possible side effects of Lindane Lotion?**

Lindane Lotion may cause serious side effects such as seizures (convulsions, fits) or death (See the section, "What is the most important information I should know about Lindane Lotion?"). Lindane Lotion can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Lotion are:

- Itching skin

- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Lotion. For more information, ask your doctor or pharmacist.

### **General Information about Lindane Lotion:**

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Lotion for any condition for which it was not prescribed. Do not give Lindane Lotion to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Lotion and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Lotion. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Lotion that is written for health professionals.

### **What are the ingredients in Lindane Lotion?**

Active Ingredient: Lindane.

Inactive Ingredients: 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylene glycol, propylparaben, purified water, stearic acid and trolamine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This medication is available only by a prescription from your doctor.

Product No.: 8546

### **Manufactured By:**

**Morton Grove Pharmaceuticals Inc.  
Morton Grove, IL 60053**

A42-8546-60 REV. 06-05

### **Distributed By:**

**Alliant Pharmaceuticals, Inc.  
Alpharetta, GA 30004**

28546A ISS. 04-05

**Medication Guide****LINDANE LOTION, USP 1%****Lindane (LIHN-dane) Lotion, USP 1%****You must read and follow all instructions before using Lindane Lotion.**

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- Wait for at least 1 hour after bathing or showering before you put Lindane Lotion on your skin. Wet or warm skin can make the Lindane Lotion go through your skin faster and may increase the risk of seizures.

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### **What should I avoid while using Lindane Lotion?**

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The most common side effects of Lindane Lotion are:

- Itching skin
- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Lotion. For more information, ask your doctor or pharmacist.

### **General Information about Lindane Lotion:**

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Lotion for any condition for which it was not prescribed. Do not give Lindane Lotion to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Lotion and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Lotion. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Lotion that is written for health professionals.

### **What are the ingredients in Lindane Lotion?**

Active Ingredient: Lindane.

Inactive Ingredients: 2-amino-2-methyl-1-propanol, carrageenan, cetyl alcohol, cocoa butter, glyceryl monostearate, methylparaben, propylene glycol, propylparaben, purified water, stearic acid and trolamine.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This medication is available only by a prescription from your doctor.

Product No.: 8546

**Manufactured By:**  
Morton Grove Pharmaceuticals, Inc.  
Morton Grove, IL 60053

**Distributed By:**  
Alliant Pharmaceuticals, Inc.  
Alpharetta, GA 30004

28546A  
ISS. 04-05

# LINDANE SHAMPOO, USP 1%

Rx only

## **Warnings:**

Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE.)

## **Neurologic Toxicity**

Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

## **Contraindications**

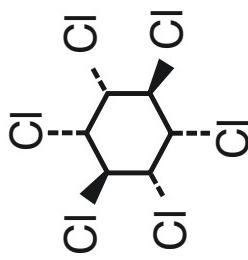
Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

## **Proper Use**

Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo. (See DOSAGE AND ADMINISTRATION.)

## **Description**

Lindane Shampoo, USP 1%, is an ectoparasiticide and ovicide effective against *Pediculosis humanis capitis* (head lice), *Pthirus pubis* (crab lice), and their ova. In addition to the active ingredient, lindane, it contains triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water to form a shampoo base. The pH may be adjusted with 10% hydrochloric acid solution and/or 10% sodium hydroxide solution. Lindane is the gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane having the following structural formula:



## **CLINICAL PHARMACOLOGY**

Lindane exerts its parasiticidal action by being directly absorbed into the parasites and their ova. Feldmann and Maibach<sup>1</sup> reported approximately 10% absorption of a lindane acetone solution applied to the forearm of human subjects and left in place for 24 hours. This vehicle was different from the approved product and the percutaneous penetration of lindane is dependent on the vehicle. Therefore, the clinical significance of these observations is unknown. Dale, et al<sup>2</sup> reported a blood level of 290 ng/mL associated with convulsions following the accidental ingestion of a lindane-containing product. Ginsburg<sup>3</sup> found a mean peak blood level of 28 ng/mL 6 hours after total body application of Lindane Lotion to scabetic infants and children. The half-life in blood was determined to be 18 hours.

Data available in the literature suggest that lindane has a rapid distribution phase followed by a longer β-elimination phase.  
There are no clinical dose ranging studies for Lindane Shampoo.

## **INDICATIONS AND USAGE**

Lindane Shampoo is indicated for the treatment of head lice (infestations of *Pediculus humanis capitis*), crab lice (infestations of *Phthirus pubis*), and their ova only in patients who

1. cannot tolerate other approved therapies, or
2. have failed treatment with other approved therapies.

Lindane Shampoo should be used in the context of an overall lice management program that includes:

- Visual inspection to ensure that the patient is currently infested with live lice (empty egg casings or “nits” can remain on hair shaft long after true infestation).
  - Manual removal of nits using a comb designed for this purpose and/or individual removal with tweezers followed by close examination of the hair and scalp.
  - Evaluation and treatment of sexual contacts simultaneously. Sexual contacts should be prescribed Lindane Shampoo only if they either have failed to respond to adequate doses of other approved therapies or are intolerant of other approved therapies.
  - All recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Caregivers applying this product to patients should wear gloves less permeable to Lindane such as nitrile, latex with neoprene or sheer vinyl, and thoroughly clean hands after application. Natural latex gloves should be avoided because they are more permeable to Lindane.

Lindane Shampoo does not prevent infestation or reinestation and should not be used to ward off a possible infestation.

## **CONTRAINdications**

Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane.

Lindane Shampoo is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.

Lindane Shampoo is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

## **WARNINGS (See boxed WARNINGS.)**

Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions.

There have been cases of adverse events reported for Lindane Shampoo and Lindane Lotion in which a serious outcome (hospitalization, disability or death) has occurred.<sup>4</sup> In approximately 20% of these cases, the shampoo and lotion were reported to have been used according to the labeled directions. Of these cases, thirteen deaths were reported, many of which were remote from the time of actual Lindane use. Lindane toxicity, verified by autopsy was the cause of one infant's death, and was the cause of death reported for an adult in a successful suicide. The direct causes of death for the other cases were attributed to reasons other than lindane. Most of these adverse events occurred with Lindane Lotion.

Infants, children, the elderly, and individuals with other skin conditions and those who weigh < 110 lbs (50 Kg) may be at a greater risk of serious neurotoxicity. (See Pediatric Use and Geriatric Use.) Animal studies have shown increased susceptibility to neurologic adverse events in younger animals. Children have a larger body surface area to volume ratio that may result in a proportionately larger systemic exposure.

Careful consideration should be given before prescribing Lindane Shampoo to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold. (See PRECAUTIONS: Drug Interactions.)

Patients should be instructed on the proper use of Lindane Shampoo, especially the amount to apply, how long to leave shampoo on, and the need to avoid retreatment. Patients should be informed that itching may occur after the successful killing of lice and

repeat treatment may not be necessary.

A Lindane Shampoo Medication Guide must be given to the patient each time Lindane Shampoo is dispensed, as required by law.

## **PRECAUTIONS**

**General:** Care should be taken to avoid contact with the eyes. If such contact occurs, eyes should be immediately flushed with water. If irritation or sensitization occurs, the patient should be advised to consult a physician.

### **Information for Patients (and Caregivers):**

- This product can be poisonous if misused.
- Other important information is found in the Medication Guide, which by law, must be dispensed with Lindane Shampoo.

If putting Lindane Shampoo on another person, the person applying shampoo should wear less permeable gloves such as nitrile, latex with neoprene, or sheer vinyl, and thoroughly clean their hands after application. Natural latex should be avoided because it is more permeable to lindane.

If the person applying Lindane Shampoo could be pregnant, contact with Lindane Shampoo should be avoided as much as possible.

If the patient could be pregnant, other treatments may be preferable.

- Use Lindane Shampoo for lice only.
- The use of oil treatments, oil based hair dressings or conditioners immediately before and after applying Lindane Shampoo should be avoided. Oils can make the Lindane Shampoo go through the skin faster and possibly increase the risk of neurotoxicity (e.g., seizures).

### **Information for Use**

- Shake Lindane Shampoo well.
- Hair should be completely dry prior to application of Lindane Shampoo.
- Use only enough Lindane Shampoo to lightly coat the hair and scalp.
- Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Special attention should be given to the fine hairs along the neck and behind the ears.
- After 4 minutes, add small quantities of water to hair until a good lather forms.
- Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces.

- Towel briskly and then remove nits with nit comb or tweezers.
  - There may be some Lindane Shampoo left in the bottle. Close the bottle with the leftover Lindane Shampoo and immediately throw away the bottle in a trash can out of the reach of children.
  - Do not cover the hair with anything that does not breathe, like a shower cap or towel.
  - Do not ingest. Keep away from mouth and eyes. If contact with eyes occurs, immediately flush eyes with water. Do not use if open wounds, cuts or sores are present, unless specifically directed by your physician.
  - Wash all recently worn clothing, underwear and pajamas, hats, and used sheets, pillowcases, and towels in very hot water or dry-clean.
  - Patients may still itch after using Lindane Shampoo. This does not mean the medicine did not work. Lindane Shampoo sometimes makes this itch even worse. Other medications can be used to soothe the itch. Do not use more Lindane Shampoo.
  - If there are any questions or concerns about the condition or use of the Lindane Shampoo, contact your physician.
- Drug Interactions:** Oils may enhance absorption of lindane, therefore, patients and caregivers applying the shampoo to others should avoid using oil treatments, or oil-based hair dressings or conditioners immediately before and after applying Lindane Shampoo.
- In addition, there are many drugs that may lower the seizure threshold, and Lindane Shampoo should be prescribed with caution in patients taking these medications. Drugs that may lower the seizure threshold include, but are not limited to the following:
- Antipsychotics
  - Antidepressants
  - Theophylline
  - Cycloserpine, mycophenolate mofetil, tacrolimus capsules
  - Penicillins, imipenem, quinolone antibiotics
  - Chloroquine sulfate, pyrimethamine
  - Isoniazid
  - Meperidine
  - Radiographic contrast agents
  - Centrally active anticholinesterases
  - Methocarbamol

**Carcinogenesis, Mutagenesis, and Fertility:** Although no studies have been conducted with Lindane Shampoo, numerous long-term feeding studies have been conducted in mice and rats to evaluate the carcinogenic potential of the technical grade of hexachlorocyclohexane as well as the alpha, beta, gamma (lindane) and delta isomers. Both oral and topical applications have been evaluated. Increased incidences of neoplasms were not clearly related to administration of lindane. The results of mutagenicity tests in bacteria do not indicate that lindane is mutagenic. Lindane did not cause sister chromatid exchange in an *in vivo* assay. The number of spermatids in the testes of rats 2 weeks after oral administration of a single dose of 30 mg/kg body weight (12 times the estimated human exposure for scabies on a body surface area comparison and assuming 50% rat oral bioavailability and 10% human bioavailability) was significantly reduced compared to the control rats.

**Pregnancy: Pregnancy Category C.** All pregnancies have a risk of birth defect, loss, or other adverse event regardless of drug exposure. Predictions of fetal risk from drug exposure rely heavily on animal data. However, animal studies may fail to predict effects in humans or may overstate such risks. Even if human data are available, the data may not be sufficient to determine whether there is an increased risk to the fetus, and individual reports of adverse outcomes in pregnancy in association with a drug may not reflect a causal relationship.

Lindane Shampoo should be given to pregnant women only if clearly needed. There are no adequate and well-controlled studies of Lindane Shampoo in pregnant women. There are no known maternal or fetal health risks described if lice are not treated, but risk of transmission of the lice to other household members is an additional consideration when deciding whether to use lice treatments. Lindane is lipophilic and may accumulate in the placenta. There has been a single case report of a stillborn infant following multiple maternal exposures during pregnancy to Lindane Lotion. The relationship of the maternal exposures to the fetal outcome is unknown.

Animal data suggest that lindane may increase the likelihood of neurologic developmental abnormalities (see below), based on findings at systemic exposures close to that expected in humans when Lindane Lotion is used to treat scabies. The immature central nervous system (as in the fetus) may have increased susceptibility to the effects of the drug. Systemic exposure resulting from Lindane Shampoo applied to hair covered areas is expected to be lower than that from Lindane Lotion that covers the entire body surface area.

Data: When rats received lindane in the diet from day 6 of gestation through day 10 of lactation, reduced pup survival, decreased pup weight and decreased weight gains during lactation, increased motor activity and decreased motor activity habituation were seen in pups at 5.6 mg/kg (2 times the estimated human exposure) but not at 1.2 mg/kg. An increased number of stillborn pups was seen at 8 mg/kg, and increased pup mortality was seen at 5.6 mg/kg. No gross abnormalities were seen in this study or in

a study in which rabbits received up to 20 mg/kg lindane by gavage on gestation day 6-18 (up to 10 times the human exposure on a body surface area comparison and assuming 50% rabbit oral bioavailability and 10% human bioavailability when lindane is applied to the entire body for the treatment of scabies).

**Nursing Mothers:** Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breast-feeding if Lindane Shampoo is applied topically to the chest area. Nursing mothers who require treatment with Lindane Shampoo should be advised of the potential risks and be instructed not to use the product on the skin as would be done for treatment of scabies. They should also be counseled to interrupt breast-feeding, with expression and discarding of milk, for at least 24 hours following use.

**Pediatric Use:** Animal data demonstrated increased risk of adverse events in the young across species. Pediatric patients have a higher surface to volume ratio and may be at risk of greater systemic exposure when Lindane Shampoo is applied. Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver. Lindane Shampoo should be used with caution in patients who weigh less than approximately 110 lbs (50 kg) and especially in infants. Lindane Shampoo is indicated only for the treatment of lice; patients with scabies should use Lindane Lotion according to the labeled instructions.

**Geriatric Use:** There have been no studies of Lindane Shampoo in the elderly. There are four postmarketing reports of deaths in elderly patients treated with Lindane Lotion for the indication of scabies. Two patients died within 24 hours of Lindane Lotion application, and the third patient died 41 days after application of Lindane Lotion, having suffered a seizure on the day of death. A fourth patient died of an unreported cause of death on the same day that Lindane Lotion treatment for scabies was administered.

## **ADVERSE REACTIONS**

Central nervous system stimulation ranging from dizziness to seizures, has been reported particularly with use of Lindane Lotion. Although seizures were almost always associated with ingestion or misuse of the product (to include repeat treatment), seizures and deaths have been reported when Lindane Shampoo was used according to directions. Irritant dermatitis from contact with this product has also been reported. (See **WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION**.)

**Postmarketing Experience:** The following adverse reactions reflect the additional postmarketing experience of Lindane Shampoo. These events include alopecia, dermatitis, headache, pain, paresthesia, pruritus and urticaria. The relationship of

some of these events to lindane therapy is unknown.

## **OVERDOSEAGE**

Contact the closest Poison Control Center in the event of suspected overdosage with Lindane Shampoo.

If accidental ingestion occurs, prompt gastric lavage should be instituted. However, since oils enhance absorption, saline cathartics for intestinal evacuation should be given rather than oil laxatives. If central nervous system manifestations occur they may be antagonized by the administration of pentobarbital, phenobarbital, or diazepam.

## **DOSAGE AND ADMINISTRATION**

Most patients will require only 1 ounce of Lindane Shampoo. Based on the length and density of hair, some patients may require 2 ounces of Lindane Shampoo.

Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Special attention should be given to the fine hairs along the neck. After 4 minutes, add small quantities of water to hair until a good lather forms. Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces. Do not prescribe more than 2 ounces for larger adults. Do not retreat. (See boxed WARNINGS.) Patients should be provided specific information on use of product. (See PRECAUTIONS: Information for Patients and Lindane Shampoo Medication Guide.)

A **Lindane Shampoo Medication Guide** must be given to the patient each time LINDANE Shampoo is dispensed as required by law. The Lindane Shampoo Medication Guide is an important part of the risk management program for the patient.

## **HOW SUPPLIED**

Lindane Shampoo, USP 1% is supplied in patient-size 2 fl oz (60 mL) bottles.  
SHAKE WELL BEFORE USING

**Store at controlled room temperature, 15 ° - 30 °C (59 ° -86 °F) [see USP].**

## **REFERENCES**

1. Feldmann, R.J. and Maibach, H.I., *Toxicol. Applied. Pharmacol.*, 28:126, 1974.
2. Dale, W.E., Curly, A. and Cueto, C. *Life Sci* 5:47, 1966.
3. Ginsburg, C.M., et al., *J. Pediatr.* 91:6, 998-1000, 1977.
4. FDA AERS database search, January 2003

**Rx Only**  
Product No.: 8547

**Manufactured By:** Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053  
**Distributed By:** Alliant Pharmaceuticals, Inc. Alpharetta, GA 30004

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## PHARMACIST—PATIENT MEDICATION GUIDE PROVIDED BELOW

### MEDICATION GUIDE

#### Lindane (LIHN-dane) Shampoo, USP 1%

**You must read and follow all instructions before using Lindane Shampoo.** Read the information you get every time you get a family member get Lindane Shampoo. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Lindane Shampoo, ask your doctor or pharmacist.

#### What is the most important information I should know about Lindane Shampoo?

**Lindane Shampoo is a poison if you do not use it the right way.** Lindane Shampoo goes through your skin and can affect your brain and nerves. Lindane Shampoo can cause seizures, also called convulsions, “fits” or epilepsy.

- Seizures and death can happen in people who use Lindane Shampoo too much or too often.
- Seizures can happen in some people even if they use Lindane Shampoo exactly as directed.

**If you or a family member has a seizure while using Lindane Shampoo, get emergency help right away.**

- Do not use Lindane Shampoo unless
  - You have lice and another medicine did not work for you, or
  - You cannot use other, safer medicines to treat your lice
- Do not use Lindane Shampoo more than 1 time to treat an attack of lice. Do not use Lindane Shampoo to treat a second attack that comes soon after the first episode. No one knows a safe time to reuse Lindane Shampoo. Even if you still itch even after using Lindane Shampoo, do not use more or use it again. Lice (bugs) can make you itch for some time even after all of the bugs are dead.
- Do not use more Lindane Shampoo than your doctor tells you.
- Do not keep Lindane Shampoo on your hair for more than 4 minutes.

- Do not put Lindane Shampoo in your mouth because it is a poison if taken by mouth. If you get Lindane Shampoo in your mouth or swallow Lindane Shampoo, call your area Poison Control Center right away and get emergency help.

## What is Lindane Shampoo?

Lindane Shampoo is a medicine that is used to treat lice. It kills lice and their eggs. Lice are very small bugs that attach to the skin on your head or pubic (crotch) area and lay eggs called nits in your hair. Some people call crotch lice “crabs”. Lice can cause severe itching. Lindane Shampoo gets into the lice and the nits and kills them. It also goes through your skin. Lindane Shampoo is used only after safer medicines have not made your lice go away. The only time Lindane Shampoo is used first is when someone cannot use safer medicines, which may include permethrin and crotamiton.

**Lindane Shampoo is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds use Lindane Shampoo only if your doctor thinks it is really needed. People who weigh less than 110 pounds and the elderly have higher chances for side effects because more Lindane may go through their skin.**

## Who should not use Lindane Shampoo?

### Do not use Lindane Shampoo:

- if you do not have lice. Lindane Shampoo does not stop you from getting lice. Lindane Shampoo only kills the lice you already have.
- if you have or have ever had seizures, also called convulsions, “fits” or epilepsy, especially if they have been hard to control.
- if you have used Lindane Shampoo in the past few months. You should see your doctor if you think that you need another treatment.
- unless it is the only medicine you can use for lice.
- if you had a bad reaction to Lindane Shampoo before. **Do not use Lindane Shampoo again.**
- if you have open sores or crusted (scabby) sores on the skin around your head and neck, or lots of broken skin.
- if you need to treat a premature or young baby. More of the applied Lindane can go through the skin of babies and go to their brains where it can harm them.
- if you have scabies. These need a different medicine that you use in a different way.
- if you are allergic to Lindane Shampoo or any of its ingredients. The active ingredient is lindane. See the end of this Medication Guide for a list of all the ingredients in Lindane Shampoo.
- while you are breast-feeding. Lindane Shampoo can get in your milk and may be fed to your baby. Your baby may get

sick. Ask your doctor for a safer medicine. If you use Lindane Shampoo, pump your breast milk and throw the milk away for at least 24 hours after using the medicine. During this time, feed your baby formula or breast milk that you stored from before you used Lindane Shampoo.

### Tell your doctor if you:

- used Lindane Shampoo in the past few months.
- ever had a seizure or problem that could increase your chances of getting a seizure (like a head injury, tumor in your brain or spinal cord, cirrhosis of the liver, or heavy alcohol drinking.)
- have HIV or AIDS. Lindane Shampoo may cause seizures even if you never had them before.
- are pregnant. Lindane Shampoo can reach your baby and may harm it. Ask your doctor for a safer medicine. Use Lindane Shampoo only if needed.
- have a sexual partner and your lice (crabs) are in your pubic (crotch) area. Your partner should get checked and treated for lice so they don't give them back to you. Don't share your Lindane Shampoo with your partner.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may increase your chances of having a seizure if you take them while using Lindane Shampoo. Especially tell your doctor if you take medicines called sedatives (drugs to help you sleep).

### How do I use Lindane Shampoo?

Before you put it on:

- **Make sure you know how to use it exactly as your doctor prescribes.**
- If you are putting Lindane Shampoo on another person, wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. **Do not use natural latex gloves because more Lindane can go through that kind of glove.** Keep the gloves on until the Lindane Shampoo is washed out of your hair. **Wash your hands well when you are done.**
- Make sure your hair and skin on your head and neck do not have any other shampoo, cream, or oil on it. Oils can make the Lindane Shampoo go through your skin faster and may increase the risk of seizures.

When you put it on:

- Shake the bottle of Lindane Shampoo well.
- Make sure your hair is clean and dry before using Lindane Shampoo, but do not wash your hair within 1 hour before using Lindane Shampoo. Use regular shampoo without conditioner and dry your hair.

- Use just enough Lindane Shampoo on your dry hair to wet your hair and scalp. Do not add water to your hair at this time. Also, put Lindane Shampoo on the short hairs at the back of your neck.
- Keep Lindane Shampoo on your hair for 4 minutes. Use a watch or clock to time yourself.
- Do not wear a shower cap or any covering on your head while you wait for the 4 minutes to pass.
- Close the bottle with the leftover Lindane Shampoo and throw it away in a trash can **out of the reach of children.**

When you are supposed to wash it off:

- After 4 minutes has passed, soap up or lather the Lindane Shampoo. Use a small amount of warm water to do this. Hot water is not safe. Then wash the Lindane Shampoo off your head. Again, use warm, but not hot water. Do not leave any Lindane Shampoo on your head or hair. It will not kill more of the lice and may continue to go through your skin and cause serious problems, such as seizures.

After you wash off Lindane Shampoo:

- Dry your hair with a towel. Use a special comb called a nit comb or tweezers to remove the dead nits (lice eggs) from your hair. Someone else will probably have to do this for you.
- All recently worn clothing, underwear, pajamas, hats, used sheets, pillowcases, and towels should be washed in very hot water or dry-cleaned.
- Do not use Lindane Shampoo again. If you think you need to use it again, you must check with your doctor to find out if and when it is most safe.

You may still itch after you have used Lindane Shampoo. This does not mean you need more Lindane Shampoo. Even after all the lice (bugs) are dead, they can still make your skin itch for a long time. Lindane Shampoo sometimes makes this itch even worse. Talk to your doctor about things you can do to soothe the itch.

### **What should I avoid while using Lindane Shampoo?**

- Do not get Lindane Shampoo in your eyes. If you do, rinse your eyes with water right away. Get medical help if your eyes keep hurting.
- Do not get Lindane Shampoo on your hands. Wear special gloves made of nitrile, latex with neoprene, or sheer vinyl. Do not use natural latex gloves. Wash your hands well when you are done.
- If you are pregnant, do not use Lindane Shampoo unless you have talked to your doctor about using it. Avoid putting Lindane Shampoo on others if you are pregnant. See the special glove advice above if you have to put Lindane Shampoo on others.

- Do not use oils on your skin or hair, just before or after using Lindane Shampoo. Oils include oil-based hair products

and conditioners.

### **What are the possible side effects of Lindane Shampoo?**

Lindane Shampoo may cause serious side effects such as seizures (convulsions, fits) or death (See the section, "What is the most important information I should know about Lindane Shampoo?"). Lindane Shampoo can also make you feel sleepy, dizzy, or can cause body shaking that you cannot control.

The most common side effects of Lindane Shampoo are:

- Itching skin
- Burning skin
- Dry skin
- A skin rash

These are not all of the possible side effects of Lindane Shampoo. For more information, ask your doctor or pharmacist.

### **General Information about Lindane Shampoo:**

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use Lindane Shampoo for any condition for which it was not prescribed. Do not give Lindane Shampoo to other people, even if they have the same symptoms that you have. It may harm them. **Keep Lindane Shampoo and all medicines out of the reach of children.** This Medication Guide summarizes the most important information about Lindane Shampoo. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Shampoo that is written for health professionals.

### **What are the ingredients in Lindane Shampoo?**

Active Ingredient: Lindane.

Inactive Ingredients: triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Lindane is only available by a prescription from your doctor.

Product No.: 8547

REV. 06-05

A42-8547-60

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28547A ISS. 04-05

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### **General Information about Lindane Shampoo:**

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#### **Keep Lindane Shampoo and all medicines out of the reach of children.**

This Medication Guide summarizes the most important information about Lindane Shampoo. If you want more information, talk with your doctor. You can ask your doctor or pharmacist for information about Lindane Shampoo that is written for health professionals.

### **What are the ingredients in Lindane Shampoo?**

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Inactive Ingredients: triethanolamine lauryl sulfate, polysorbate 60, hydrochloric acid, acetone and purified water.

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28547A  
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## *Information DOWNLOADS ON LINDANE*

### Information DOWNLOADS

Lindane lotion prescription labeling

Lindane shampoo prescription labeling

Lindane lotion medication guide

Lindane shampoo medication guide

U.S. Food and Drug Administration's (FDA) Response to Citizen's Petition, 1997

U.S. Centers for Disease Control and Prevention (CDC) 2006 Sexually Transmitted Disease Treatment Guidelines

U.S. Food and Drug Administration (FDA) Assessment Memorandum on Lindane, posted 2003

U.S. Environmental Protection Agency (EPA) Revised Assessment of Risk From Use of Lindane for Treatment of Lice and Scabies, July 2002

U.S. EPA Response to Comments on the 2002 Lindane RED, July 2006

U.S. EPA Evaluation of Lindane Carcinogenic Potential, 2001

World Health Organization Background Document on Lindane for Drinking-Water Quality Guidelines. 2004.

*Points of View on Lindane:*

FOOD AND DRUG ADMINISTRATION

ENVIRONMENTAL PROTECTION AGENCY

CENTERS FOR DISEASE CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC OPINIONS

Please See Important Safety Information on Lindane

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[Commitment to Public Health and Safety](#) | [Lindane Prescribing Information](#) | [FDA Information on Lindane](#)

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## Important SAFETY INFORMATION

[Information DOWNLOADS](#)

When used as directed, lindane medications are relatively safe and effective. The most commonly reported side effects include itching skin, burning skin, dry skin, and rash. Other *Points of View on Lindane*: reported adverse events include: dizziness, headache, pain, paresthesia (tingling), hives, and alopecia (hair loss). However, the relationship of some of these effects to lindane therapy is unclear.

[FOOD AND DRUG  
ADMINISTRATION](#)

Serious adverse events with lindane medications, such as seizures and death, are rare, and have almost always resulted from product misuse (e.g., swallowing large quantities, prolonged or repeated application). Lindane medications are now limited to single-use 2 oz. bottles to minimize this risk. Please see Boxed Warnings below.

[ENVIRONMENTAL  
PROTECTION AGENCY](#)

[CENTERS FOR DISEASE  
CONTROL AND PREVENTION](#)

[MEDICAL & SCIENTIFIC  
OPINIONS](#)

### Lindane lotion USP, 1% Rx Only

#### WARNINGS:

Lindane lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies

#### Neurologic Toxicity

Seizures and deaths have been reported following lindane lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane lotion should be used with caution in infants, children, the elderly, and individuals with other skin conditions (e.g, atopic dermatitis, psoriasis) and in those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity

#### Contraindications

Lindane lotion is contraindicated in premature infants and individuals with known uncontrolled seizure disorders

#### Proper Use

Instruct patients on the proper use of lindane lotion, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of scabies and is not necessarily an indication for re-treatment with lindane lotion

## Lindane shampoo USP, 1% Rx Only

### **WARNINGS:**

Lindane shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice

### **Neurologic Toxicity**

Seizures and deaths have been reported following lindane shampoo use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane shampoo should be used with caution in infants, children, the elderly, and individuals with other skin conditions, and in those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity

### **Contraindications**

Lindane shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders

### **Proper Use**

Instruct patients on the proper use of lindane shampoo, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for re-treatment with lindane shampoo

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## What is LINDANE?

Healthcare vs. Agricultural Uses   Regulatory History   **The Need for Second-line Medications**   [Information DOWNLOADS](#)

### The Need for Second-line Medications like Lindane

Scabies and lice infestations remain common public health problems, despite available treatments. The inherent limitations of first-line medications and the unpredictable and increased incidence of treatment-resistant forms of scabies and lice necessitate the need for a range of treatment alternatives. Second-line therapies, more specifically, provide a valuable "last resort" for patients who have nowhere else to turn.

The Food and Drug Administration (FDA) has repeatedly and consistently maintained its position that lindane medications provide healthcare benefits that outweigh potential risks when used appropriately.<sup>1</sup> This position is based on extensive lindane reviews by medical and scientific experts and more than 50 years of clinical experience with lindane medications in healthcare.

*Lindane lotion and lindane shampoo are approved for the second-line treatment of scabies and lice, meaning they are only prescribed for patients who have failed or cannot tolerate first-line medications<sup>2,3</sup>*

*Points of View on Lindane:*

[FOOD AND DRUG ADMINISTRATION](#)  
[ENVIRONMENTAL PROTECTION AGENCY](#)  
[CENTERS FOR DISEASE CONTROL AND PREVENTION](#)  
[MEDICAL & SCIENTIFIC OPINIONS](#)

### Scabies and lice continue to impact public health

Scabies and lice are highly-contagious parasitic infestations of the skin that carry significant health risks if left untreated or treated unsuccessfully. (See [Understanding Scabies and Lice](#))

### Scabies and lice remain an ongoing challenge:

Worldwide, there are hundreds of millions of people infested with scabies and lice, reaching epidemic proportions in some areas and settings<sup>4-6</sup>

Scabies and lice have medical, social, and economic consequences that are estimated to cost hundreds of millions of dollars each year<sup>7</sup>

### *Limitations of First-Line Scabies and Lice Treatments*

*No treatment for scabies or lice is 100% effective<sup>6</sup>*

*Some patients cannot tolerate first-line medications due to allergic reactions or other adverse side effects<sup>6</sup>*

*Resistance of scabies and lice to approved medications is on the rise globally,*

*underscoring the need for multiple treatment options<sup>4,5</sup>*

Currently available treatments for scabies and lice have significant limitations. Reducing the number of therapeutic options would be a disservice to patients who have limited options.

Please See Important Safety Information on Lindane

**References:**

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: <http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm>.
2. Lindane lotion, USP, 1% prescribing information. Updated March 28, 2003. Available at: <http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf>.
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## Understanding SCABIES AND LICE

Infectious Disease Perspective Incidence and Health Risks Diagnosis **Treatment Options** Resistance [Information DOWNLOADS](#)

### Treatment Options for Scabies and Lice

*Points of View on Lindane:*

Topical medications, including prescription and over-the-counter remedies that are applied to the skin, are considered the mainstay of scabies and lice treatment. Unfortunately, none are 100% effective and some patients are intolerant of some of these medications because of allergies or adverse side effects. Moreover, treatment-resistant forms of scabies and lice have increased in recent years, further compromising the effectiveness of available medications. Manual removal of head lice and their nits with special combs is appropriate in select situations, but is labor intensive and not a preferred method.<sup>1,2</sup> As such, a range of first- and second-line treatment options is necessary for effective disease control and individualized patient care.

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FDA-approved therapies for scabies are relatively limited

**Medications that are currently approved by the Food and Drug Administration (FDA) for the topical treatment of scabies include:**

Permethrin

Crotamiton

Lindane

An oral medication called ivermectin is also used for the management of scabies, but is not FDA-approved for this indication.<sup>3</sup> Additional information, including links to respective product labels, can be found in the table below.

*Healthcare providers have few effective treatment options for managing scabies.*

Medications Used To Treat Scabies			
<b>Medication (brand name)</b>	<b>Availability</b>	<b>CDC Position*</b>	<b>FDA Position</b>
Permethrin 5% cream <sup>4,5</sup> (Elimite®, Acticin®)	Prescription only	Recommended regimen	Approved first line
Crotamiton 10% cream or lotion <sup>6</sup>	Prescription only	None	Approved first line

( <u>Eurax®</u> )			
<u>Lindane 1% lotion</u> <sup>7</sup> (generic only)	Prescription only	Alternative regimen	Approved second line <sup>†</sup>
Ivermectin oral tablets <sup>8</sup> ( <u>Stromectol®</u> )	Prescription only	Recommended regimen— off-label use	Not approved for scabies

\* As listed in 2006 Centers for Disease Control and Prevention's (CDC's) Sexually Transmitted Disease Treatment Guidelines.<sup>9</sup>

<sup>†</sup>Lindane is indicated for patients who have failed or cannot tolerate first-line medications.

*Treatment failure with scabies medications occurs for many reasons:<sup>10</sup>*

*Resistance (demonstrated for all scabicides)*

*Improper application (e.g., only applied to selected areas)*

*Inadequate application (e.g., dilution, lack of compliance with regimen)*

*Reinfestation (e.g., failure to treat close social contacts or launder  
clothes/ bedding)*

## Lice pose an ongoing treatment challenge

Lice infestation remains a significant public health problem in the U.S. despite the available treatments. Medications commonly used to treat lice include:

- Pyrethrins
- Permethrin
- Lindane
- Malathion

An oral medication called ivermectin is also used to treat lice but is not FDA approved for this indication.<sup>8,11</sup> Additional information, including links to respective product information, can be found in the table below.

Medications Used to Treat Head Lice and Pubic (crab) Lice			
<b>Medication (brand name)</b>	<b>Availability</b>	<b>CDC position— pubic lice only*</b>	<b>FDA position</b>
Pyrethrins [0.33%] with piperonyl butoxide [4%] <sup>12</sup> ( <u>Rid®</u> )	Over-the- counter	Recommended regimen	Conforms to FDA over- the-counter drug monograph 21CFR 358.610
Permethrin 1% crème rinse <sup>13</sup> ( <u>Nix®</u> )	Over-the- counter	Recommended regimen	Approved for first-line treatment of <u>head lice only</u>
Malathion 0.5% <sup>14</sup> ( <u>Ovide®</u> )	Prescription only	Alternative regimen	Approved for first-line treatment of <u>head lice only</u>
Lindane 1% shampoo <sup>15</sup>	Prescription only	Second-line regimen	Approved for second-line <sup>†</sup> treatment of both <u>head lice</u>

(generic only)			<u>and pubic (crab) lice</u>
Ivermectin oral tablets <sup>8</sup> (Stromectol®)	Prescription only	Alternative regimen—off-label use	Not approved for lice

\* As listed in 2006 Centers for Disease Control and Prevention's (CDC's) Sexually Transmitted Disease Treatment Guidelines.<sup>9</sup>

<sup>†</sup>Lindane is indicated for patients who have failed or cannot tolerate first-line medications.

***Treatment failure with lice medications can occur for many reasons:<sup>16</sup>***

*Resistance (a concern with all available lice medications)*

*Poor compliance with treatment and medication regimens*

*Application to wet hair (i.e., dilutes medication and causes lice to shut down their breathing, further limiting their exposure to medication)*

*Reinfestation (e.g., re-exposure to lice or failure to treat personal social contacts)*

### **Manual removal (â€œwet combingâ€) of nits is not a preferred method for treating lice**

Manual removal is relatively labor intensive and involves the combing of wet hair (“wet combing”) with a special comb for 15 to 30 minutes or more every 3 to 4 days for several weeks<sup>17</sup> (See: Fact Checker)

Moreover, evidence for the effectiveness of wet combing in controlling lice infestations is generally lacking<sup>18</sup>

The CDC and The American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over wet combing for the treatment of head lice<sup>1,2</sup>

Nonetheless, wet combing is an appropriate alternative when the use of medications is not appropriate (e.g., lindane should be used with caution in infants, children, the elderly, pregnant or lactating women, individuals with other skin conditions and in those who weigh <110 lbs.)

Please See Important Safety Information on Lindane

#### **References:**

1. Frankowski BL, Weiner LB. Head lice: Guidance for the clinician in rendering pediatric care. *Pediatrics*. 2002;110:638–643.
2. U.S. Centers for Disease Control and Prevention (CDC). Parasitic Disease Information: Head Lice Fact Sheet. 2005. Available at: [http://www.cdc.gov/ncidod/dpd/parasites/lice/factsht\\_head\\_lice\\_treating.htm](http://www.cdc.gov/ncidod/dpd/parasites/lice/factsht_head_lice_treating.htm).
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5. Elimite® (permethrin cream 5%) drug information. Available at: [http://www.drugs.com/PDR/Elimite\\_Cream.html](http://www.drugs.com/PDR/Elimite_Cream.html).
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- [http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf.](http://www.fda.gov/cder/foi/label/2003/006309lotionlbl.pdf)
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  9. U.S. Centers for Disease Control and Prevention (CDC). Ectoparasitic infections. Sexually transmitted diseases treatment guidelines, 2006. *MMWR Recomm Rep.* 2006, August 10;55 (No. RR-11):79-80. Web version available at: <http://www.cdc.gov/std/treatment/>.
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  14. Ovide® (malathion lotion) prescribing information. Available at: [http://www.ovide4headlice.com/Headlice\\_OVIDEmalathionLotion.html.](http://www.ovide4headlice.com/Headlice_OVIDEmalathionLotion.html)
  15. Lindane shampoo, USP, 1% prescribing information. Updated March 28, 2003. Available at: [http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf.](http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf)
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  17. Roberts RJ. Clinical practice. Head lice. *N Engl J Med.* 2002;346(21):1645-50.
  18. Downs AM. Managing head lice in an era of increasing resistance to insecticides. *Am J Clin Dermatol.* 2004;5(3):169-177.

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## Lindane Product ADVANCEMENTS

Packaging Prescription Product Labeling Patient Education Ongoing Research Investments

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In recent years, a number of important changes to product packaging and prescription labeling have been made for lindane lotion and lindane shampoo in the U.S. market. Single-use containers and patient-friendly medication guides, in particular, have dramatically reduced the potential risk of serious adverse effects. The detailed prescribing information written for healthcare professionals, who prescribe lindane, has also been repeatedly updated for safety in collaboration with the Food and Drug Administration (FDA). (See Lindane Regulatory History) Moreover, ongoing investments in research and development have been designed to further advance the benefit-safety balance of lindane medications for the future. (See MGP Commitment)

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## Lindane Product ADVANCEMENTS

Packaging Prescription Product Labeling Patient Education Ongoing Research Investments

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### Prescription Packaging of Lindane

*Points of View on Lindane:*

Both the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) agree that lindane medications are safe when used properly and that the majority of serious adverse events have resulted from product misuse (e.g., swallowing large quantities, excess application).<sup>1,2</sup> To minimize this risk and enhance product safety, lindane lotions and shampoos manufactured in the U.S. have been restricted to single-use, 2 oz. bottle packaging since 2003. Now, patients filling their lindane prescriptions receive just enough medication for a single treatment.<sup>1</sup>

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Single-use 2 oz. packaging dramatically minimizes risk for misuse of lindane medications

**Minimizes risk** of excess application or reapplication of lindane

**Minimizes risk** of accidental or intentional oral ingestion of large quantities of lindane

**Minimizes risk** of use of leftover medication by persons other than the patient for whom lindane was prescribed (including others who may not actually be infected with scabies or lice)



Lindane products	U.S. <sup>3-5</sup>	Canada <sup>6</sup>
Regulatory status	Prescription <u>only</u>	O.T.C.* no prescription required
Packaging	2 oz., single-use bottle <u>only</u>	Up to 17 oz. bottle; enough lindane for 8 or more treatments

\* O.T.C.=over-the-counter medication

### Non-U.S. lindane packaging increases misuse potential

The availability of U.S.-manufactured lindane medications eliminates the need for patients with no other treatment options to turn to foreign suppliers, through websites or alternative channels, for less-regulated lindane products, where the risk for misuse and serious side effects is much greater.

For example, the large, 17 oz. bottle of lindane sold in Canada makes it easier for less-informed patients and caregivers to misuse lindane, and increases the risk of serious adverse events from accidental or intentional ingestion of large amounts of lindane. Moreover, lindane is available without a prescription from Canadian sources and is easily purchased by patients who are not required to see a healthcare provider for proper diagnosis and counseling.

The FDA has recently warned Canadian drug importers about consistent misrepresentation of the safety of foreign drug products and failure to include important patient safety information<sup>7</sup>

Keeping lindane on the market in the U.S. as a prescription therapy regulated by the FDA

protects the American public from the potential dangers discussed above.

Please See Important Safety Information on Lindane

**References:**

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: <http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm>.
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## Lindane Product ADVANCEMENTS

Packaging Prescription Product Labeling Patient Education

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### Prescription Lindane Labeling

The professional product labeling for lindane medications (also referred to as "full prescribing information") provides physicians and other healthcare providers with important information on the benefits, risks, and appropriate use of these lindane prescription therapies. Over the past three decades, the prescription labeling for lindane lotion and lindane shampoo has been updated for safety as new information has become available and reviewed by the Food and Drug Administration (FDA). (See [Lindane Regulatory History](#)) These updates, implemented by the U.S. manufacturer, help to maximize the safety of lindane medications in healthcare practice.

*Points of View on Lindane:*

[FOOD AND DRUG](#)

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Recent changes in lindane prescription labeling improve the benefit-safety balance of lindane medications

In 2003, a boxed warning was added to lindane professional labeling to raise awareness among healthcare professionals of the potential risks for neurologic toxicity and proper use of lindane medications for the treatment of scabies and lice, including:<sup>1</sup>

**Second-line use**, for patients who have failed or who cannot tolerate approved first-line medications

**Risk of neurologic toxicity**, particularly with product misuse, and risks in infants, children, the elderly, individuals with other skin conditions, and patients weighing <110 lbs. (label suggests using lindane only with caution in these groups of patients) (See [Adverse Events](#))

**Contraindications** in premature infants and persons with seizure history (label suggests never using lindane in these patients)

**Proper use instructions**, including how much lindane medication should be applied and how long it should be left on

The exact language in the current boxed warning for lindane lotion is shown below. Similar language is also contained in the boxed warning for lindane shampoo.<sup>2,3</sup>

#### WARNINGS:

Lindane lotion should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of scabies (See [INDICATIONS AND USAGE](#).)

### Neurologic Toxicity

Seizures and deaths have been reported following lindane lotion use with repeat or prolonged application, but also in rare cases following a single application used according to directions. Lindane lotion should be used with caution in infants, children, the elderly, and individuals with other skin conditions (e.g., atopic dermatitis, psoriasis) and in those who weigh <110 lbs (50 kg) as they may be at risk of serious neurotoxicity.

### Contraindications

Lindane lotion use is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.

### Proper Use

Instruct patients on the proper use of lindane lotion, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of scabies and is not necessarily an indication for re-treatment with lindane lotion (See DOSAGE AND ADMINISTRATION.)

Professional labeling of U.S. lindane products promotes safety

Lindane products	U.S. <sup>2-4</sup>	Canada <sup>5</sup>
Regulatory status	Prescription <u>only</u>	O.T.C.* , no prescription required
Professional product labeling	Reviewed and updated in close collaboration with the FDA; provides detailed scientific information and clinical guidance specifically for healthcare professionals	Due to O.T.C.* status, no professional labeling is required; package insert contains only information for patients, who may be unaware of the importance of consulting with a physician, nurse, or pharmacist

\* O.T.C.=over-the-counter medication

Please See Important Safety Information on Lindane

### References:

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: <http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm>.
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## Lindane Product ADVANCEMENTS

Packaging | Prescription Product Labeling | Patient Education | Ongoing Research Investments

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### Lindane Patient Education

*Points of View on Lindane:*

Appropriate use of lindane medications by patients and caregivers is an important aspect of their safety and effectiveness. In 2003, the Food and Drug Administration (FDA), in collaboration with the U.S. manufacturer, addressed this issue with the creation of patient-friendly medication guides for both lindane lotion and lindane shampoo. These guides are now required by law to be dispensed by pharmacists with every new lindane prescription.<sup>1</sup>

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Lindane medication guides are designed to enhance lindane safety:<sup>2,3</sup>

Written in plain English, the medication guides help physicians and pharmacists to educate patients and caregivers on potential risks, proper use, and contraindications. The medication guides are integrated into the newer single-use packaging of lindane lotion and shampoo to ensure they are dispensed with each prescription.

Well-informed patients are less likely to misuse medications like lindane

Lindane products	U.S. <sup>2-6</sup>	Canada <sup>7</sup>
Regulatory status	Prescription <u>only</u>	O.T.C.* no prescription required
Patient-friendly medication guide	Packaged with each bottle and dispensed by pharmacist with each prescription— <u>required by law</u>	None

\* O.T.C.=over-the-counter medication

Critical information covered in Medication Guides for lindane lotion and shampoo:<sup>2,3</sup>

What is lindane lotion/shampoo?

Who should not use lindane lotion/shampoo?

How do I use lindane lotion/shampoo?

Before you put it on

When you put it on

When you are supposed to wash it off

After you wash it off

What should I avoid while using lindane lotion/shampoo?



[click to enlarge](#)

Lindane lotion and shampoo packaging ensures that the medication guide stays together with the bottle and is easily accessed by pharmacists, patients, and caregivers

What are the ingredients in lindane lotion/shampoo?

Please See [Important Safety Information on Lindane](#)

**References:**

1. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: <http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm>.
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## Lindane Product ADVANCEMENTS

Packaging Prescription Product Labeling

Patient Education

Ongoing Research Investments

Information DOWNLOADS

### Ongoing Lindane Research Investments

*Points of View on Lindane:*

As a U.S. manufacturer of lindane medications, Morton Grove Pharmaceuticals, Inc. (MGP) recognizes the public health need to preserve lindane as a second-line therapy for the treatment of scabies and lice. Given that the majority of lindane safety issues relate to the potential for misuse, MGP has taken important measures to minimize this risk—and continues to do so.

FOOD AND DRUG

ADMINISTRATION

ENVIRONMENTAL

PROTECTION AGENCY

CENTERS FOR DISEASE

CONTROL AND PREVENTION

MEDICAL & SCIENTIFIC

OPINIONS

Working in close collaboration with regulatory experts, MGP has taken the lead in developing and implementing a lindane clinical research program. This ongoing investment is designed to further enhance the benefit-safety balance of lindane medications.

The current lindane research program has multiple goals<sup>1</sup>

Evaluate safety of lindane medications

Evaluate efficacy of lindane medications

Evaluate safe and effective dose ranges for different patient types

Advancing lindane safety remains a priority

MGP has played an integral role in improving the safety of lindane medications for patients in the U.S. The company is proud of its work with regulatory experts at the Food and Drug Administration (FDA), and continues to look for new ways to enhance the safety and clinical utility of lindane medications through research and development efforts.

#### ***Lindane safety advancements implemented by MGP<sup>2-7</sup>***

***Single-use packaging:*** Modified from the original 16 oz. bottle to small, single-use, 2 oz. bottles of lindane lotion and lindane shampoo

***Boxed warnings:*** Updated lindane label for healthcare professionals, highlighting important risks (including neurologic toxicities) and patient selection criteria

***Patient-friendly lindane medication guide:*** Packaged with each bottle and required by law to be dispensed by pharmacists with each lindane prescription to educate patients and caregivers on risks and appropriate use

Please See Important Safety Information on Lindane

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